FEDERAL TRADE COMMISSION

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FEDERAL TRADE COMMISSION

In the Matter of:	)
SCHERING-PLOUGH CORPORATION,	)
a corporation,	)
and	)
UPSHER-SMITH LABORATORIES,	) File No. D09297
a corporation,	)
and	)
AMERICAN HOME PRODUCTS,	)
a corporation.	)
----------	)

Tuesday, February 19, 2002

9:30 a.m.

TRIAL VOLUME 18

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Susanne Bergling, RMR

For The Record, Inc.
Waldorf, Maryland
(301) 870-8025

APPEARANCES:

ON BEHALF OF THE FEDERAL TRADE COMMISSION:

KAREN G. BOKAT, Attorney
PHILIP EISENSTAT, Attorney
SETH C. SILBER, Attorney
KARAN SINGH, Attorney
Federal Trade Commission
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
(202) 326-2912

ON BEHALF OF SCHERING-PLOUGH CORPORATION:

JOHN W. NIELDS, Attorney
LAURA S. SHORES, Attorney
MARC G. SCHILDKRAUT, Attorney
DIANE BIERI, Attorney
Howrey, Simon, Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2402
(202) 783-0800

ON BEHALF OF UPSHER-SMITH LABORATORIES:

ROBERT D. PAUL, Attorney
J. MARK GIDLEY, Attorney
CHRISTOPHER M. CURRAN, Attorney
White & Case, LLP
601 Thirteenth Street, N.W.
Suite 600 South
Washington, D.C. 20005-3805
(202) 626-3610

ON BEHALF OF AMERICAN HOME PRODUCTS:

BARBARA H. WOOTTON, Attorney
Arnold & Porter
555 Twelfth Street, N.W.
Washington, D.C. 20004-1206
(202) 942-5667

P R O C E E D I N G S

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JUDGE CHAPPELL: Back on the record, docket 9297.

Mr. Nields?

MR. NIELDS: Your Honor, I have at least something of a status report.

JUDGE CHAPPELL: Okay.

MR. NIELDS: First of all, the date of January -- February 25th is okay.

JUDGE CHAPPELL: All right.

MR. NIELDS: And I think Your Honor indicated that we would go until 3:30 that day.

JUDGE CHAPPELL: Right, we will go that day until about 3:15. I have another hearing at 3:30. So, we can get almost a full day in.

MR. NIELDS: Okay. Now, we have made some progress on trimming and predicting. We believe, Your Honor, that Schering can put in its direct case with eight or nine additional witnesses, which is a smaller number than we talked about at the end of last week.

In addition, of those eight or nine, there are four that we have discussed with complaint counsel the following sort of format that may save us some time. We would use a written direct. In other words, we

would have a narrative direct that would be introduced into the record. The witness would give a very brief, from the witness stand, summary of that, and then there would be live cross and redirect.

JUDGE CHAPPELL: How much time do you think that would save per witness?

MR. NIELDS: On direct -- the witnesses differ, Your Honor, but I'm thinking we're saving at least an hour per witness and maybe more than that. I have a hope, and no one has guaranteed this to me, nobody has even offered it to me, but I have a hope that in some fashion or another the fact that it's a briefer live direct encourages a slightly briefer cross, but I have no -- I have no assurance of that.

JUDGE CHAPPELL: So, this is a submission that's not part of a deposition transcript?

MR. NIELDS: Correct.

JUDGE CHAPPELL: I would have no problem with that if the opponents don't object. So, the witness is going to confirm that. You are going to lay a foundation for that statement.

MR. NIELDS: Yes, exactly. The witness would say this is his or her statement, and it would be adopted and then put into the record. I think that would save a significant amount of in-court time.

JUDGE CHAPPELL: Well, the point I wanted to make clear is even though we are running out of time, I am not going to force any party to cut your case short. You have the right to put on any witness you think you need to prove your case, and that goes for every party. I just want to be clear about that.

MR. NIELDS: We appreciate that, Your Honor.

JUDGE CHAPPELL: You know, whatever we have to do, you know, to get the trial briefs -- the post-trial briefs in and get the opinion out, you know, I'll do and you guys will do, I understand that, but I am not going to cut short anybody's right to have a full and fair trial.

MR. NIELDS: We appreciate that.

If this works, Your Honor, and we're optimistic that it will, our prediction would be that Schering's case should take approximately an additional five trial days. That could be off in either direction depending on the length of cross, but that would be my pretty good estimate, I think, of how much more time there will be for Schering's direct case. It won't all be consecutive, because as we work out these logistics and for other reasons, Upsher's case will start to go in sometime this week, but I think that gives you a pretty good idea of how much time Schering will need for its

direct case.

JUDGE CHAPPELL: Well, and as I said earlier, I'm loath to extend the one-year deadline, and I'm not going to suggest anything, but if it gets to the point where we absolutely -- if the parties need time to do valid post-trial briefs, because those post-trial briefs are going to help me with valid and proper record cites, at that point, I will revisit the issue of whether I would favorably look upon a motion to extend the deadline. I'm not ruling anything out. That would be speculative, but I understand that we're all going to be under a lot of time and pressure. I also understand that it will help me if the parties have time to do better briefs after trial.

MR. NIELDS: Very well, Your Honor. We appreciate that.

JUDGE CHAPPELL: And I have developed some room to dance in one of my other cases, and I might be able to make some room there. I don't want to be in a position of being in the middle of a trial and having to get a decision out at the same time, although if that happens, it happens.

Anything else?

MR. NIELDS: No, Your Honor. We have on tap today two witnesses. The first is Mr. Audibert, and as

the Court may recall, he is the Schering person that did the evaluation of the Niacor-SR product, and then we will have Mr. Furniss, who is an expert on pricing overseas, and he is from overseas, and we're hoping that we'll get him on and off today as well, but, of course, that depends on the length of the cross.

JUDGE CHAPPELL: Okay.

MR. NIELDS: And then tomorrow we will have Thomas Lauda, who is also involved in the Niacor-SR evaluation.

JUDGE CHAPPELL: And we will need to cut off no later than 5:00 today. We'll get almost a full day in.

MR. NIELDS: Okay.

JUDGE CHAPPELL: Just try to -- let's all try to keep to remember that, 5:00 cut-off today.

MR. NIELDS: Very well.

JUDGE CHAPPELL: Ready?

MR. NIELDS: Yes, we call James Audibert, and I think he's right outside and will be right in, Your Honor.

JUDGE CHAPPELL: Good morning, sir. Raise your right hand, please.

Whereupon--

JAMES M. AUDIBERT

a witness, called for examination, having been first

duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: State your full name for the record, please.

THE WITNESS: My name is James M. Audibert.

DIRECT EXAMINATION

BY MR. NIELDS:

Q. Good morning, Mr. Audibert.

How are you employed?

A. I am employed by the Schering-Plough Research Institute.

Q. And do you have a title in that institute?

A. Yes, my position is senior director for commercial optimization.

Q. Let's go back over your background. Can you describe your educational history?

A. Yes. I have a Bachelor of Science degree in pharmacy from Northeastern University College of Pharmacy, and I also have a Master's of Science degree in pharmacology, also from Northeastern University College of Pharmacy.

Q. And when did you receive your Bachelor's?

A. I received my Bachelor's in 1974 and my Master's in 1982.

Q. Can you describe your job history since you got your Bachelor's?

A. Yes, after I graduated pharmacy school in 1974, I worked for two years as a retail -- as a practicing pharmacy in a retail pharmacy. Then from 19 --

Q. Where was that?

A. In Haverhill, Massachusetts.

Q. And you were actually a pharmacist?

A. Yes. And then from -- in 1976, I went to work for a pharmaceutical company in Haverhill called Dooner, D O O N E R, Laboratories, and I worked with that through 1980. In 1977, Dooner was acquired by William H. Rorer, which was also a pharmaceutical company.

Q. All right, so you worked for Dooner and then Dooner/Rorer from '76 to '80?

A. That's correct.

Q. And can you describe briefly what the business of Dooner and Rorer was?

A. Dooner was a pharmaceutical company that specialized in taking older compounds and developing them into new sustained release products and marketing them, as well as some antihistamines, cold products.

Q. And what were your responsibilities at Dooner and Rorer?

A. My primary responsibility was handling medical inquiries from both our sales force as well as outside

pharmacists and physicians about our particular products. And my other responsibilities had to do with coordinating clinical studies that were being done with our particular products.

Q. And what did you do in terms of coordinating clinical studies?

A. That would involve helping to put together a protocol with an outside clinical investigator, monitoring the clinical study. When the study was completed, working with the clinical investigator to analyze the data, working with the investigator to put together the final study report, and then I would take that final study report and put it into a dossier to submit to the Food and Drug Administration.

Q. And when you refer to clinical trials, these are trials of patients receiving drugs?

A. Patients or in some cases the bioavailability studies, which are usually done with healthy -- healthy volunteers.

Q. Okay. Now, that takes us to 1980. What did you do in 1980?

A. In 1980, I went to work for Key Pharmaceuticals, which was a pharmaceutical company based in Miami, and I --

Q. What was the business of Key Pharmaceuticals?

A. The business of Key Pharmaceuticals was actually very similar to that of Dooner, we were taking older compounds, which had been known to be safe and efficacious but perhaps with certain limitations because of side effects or efficacy, and putting them in new drug delivery sustained release technology to make the products either more efficacious or safer.

Q. Was Key Pharmaceuticals then owned by Schering?

A. No.

Q. And what kinds of jobs did you hold at Key Pharmaceuticals?

A. I spent two years in the sales organization, three years in the research organization, and then two years back in the sales organization where it was sort of a hybrid job, doing sales as well as some of the technical jobs I had done when I was in the research organization.

Q. And what happened next? What does that take us up to, about 1987?

A. In 1987, Schering purchased Key in mid-1986, and in March of 1987, I moved to New Jersey and went into the marketing department for Schering.

Q. Okay. And can you briefly describe the various positions you've held at Schering?

A. At Schering, I was a product manager, then I

was a marketing director, then I was a field director and marketing director of our managed care group, and then I went into our global marketing area in 1995. So, they were predominantly -- they were sales and marketing positions.

Q. And how long did you stay in global marketing at Schering?

A. I was there from April 1995 until September 2000.

Q. And what job did you take in September 2000?

A. In my current job in SPRI.

Q. And what are your duties in your current job?

A. My current job involves working with both the commercial groups within the company as well as the research groups in the company to make sure their -- the development strategies behind the product are designed to make sure the product is a success in the marketplace. So, this requires my understanding both the business side as well as the technical side of our products.

Q. And was there a reason you were selected for that particular job?

A. Because of my background, again, both in the science as well as the commercial sides.

Q. Over the course of your career in the

pharmaceutical industry, have you had experience in research and development?

A. Yes.

Q. And I think you've already described the duties you had at Dooner that related to research, and you mentioned you were in the R&D section of Key from 1982 to 1985. Can you describe your duties at Key during that period?

A. Actually, my responsibilities at Key were actually very similar to what I had been doing at Dooner, and that involved two things. One is handling inquiries from physicians, pharmacists, as well as our sales force, but I was also very involved with conducting clinical studies with various products, and these would involve both clinical and bioavailability studies.

Q. And again, what was your functions -- what were your functions on these clinical studies?

A. Again, my functions would be assisting in creating the protocol, monitoring these studies. When the studies were done, analyzing the results with the investigators, putting together the report. In Key, I was not involved with interfacing with the regulatory authorities as I had been with Dooner/Rorer.

Q. What products did you work on in R&D at Key?

A. At Key, the products I worked on were two sustained release theophylline products, Theo-Dur tablets and Theo-Dur Sprinkle, and these products are sustained release theophylline products used for asthma, bronchitis. I also worked on a product called Nitro-Dur, which was a sustained release nitroglycerine patch that patients wore on their skin for angina, and I also worked on an extended release potassium chloride product called K-Dur.

Q. What was the purpose of the clinical trials that you worked on?

A. Some of the studies were done to submit to the Food and Drug Administration for labeling changes, so they were registration studies, while other studies were what we called phase IV studies. They were studies done to enhance the profile of the product, to test the product, say, against a competitor, perhaps test the product with a particular patient population.

Q. Now, you mentioned that in addition to this clinical trial supervision responsibility that you answered questions from the medical community about your products. Could you describe those functions just a little bit more?

A. Yes. One way would be we would get written requests or phone calls from pharmacists, physicians or

our sales force that I would assist in answering. The other thing that I did was, because of my expertise in the area of sustained release theophylline, I would frequently represent the company as an expert for them on the product to outside medical groups. These could be state Medicaid formularies that are looking to -- whether they should put another sustained release formulary. It could be hospital formulary group, could be meeting with a group of physicians. It varied, but again, I was sort of one of the product experts for Theo-Dur.

Q. I think you've already answered this in a sense, but have you had experience over your career in the pharmaceutical industry with sustained or extended release products?

A. Yes.

Q. And could you tell us what those products were?

A. The products I -- again, with Dooner/Rorer, the two products were Slo-phyllin and Slo-bid gyro-caps, those were both sustained release theophylline products. Then with Key, it was Theo-Dur tablets and Theo-Dur sprinkle, which are both sustained release theophylline products, Nitro-Dur, which was a --

Q. Let's just stay with the Theo-Dur sustained release theophylline product for the moment. This is a

Key product, I take it?

A. Yes.

Q. And was that a product that was successful in the marketplace?

A. Very successful. It was the product leader, market leader. In fact, it was the first $100 million product for Schering-Plough.

Q. When you say "product leader," do you mean in the theophylline field?

A. Yes, in the theophylline market, yes.

Q. So, there were other companies selling theophylline products as well?

A. Yes.

Q. Okay, I think I interrupted you when you were starting to describe Nitro-Dur.

A. Nitro-Dur is a sustained release nitroglycerin patch that patients wear for their angina. I worked on that, as well as K-Dur, which is an extended release potassium chloride tablet.

Q. And were those two products successful in the marketplace?

A. Yes, they were both market leaders, both between $200-$300 million a year in sales.

Q. Now, Mr. Audibert, you said that you had several jobs in the marketing field, one of them global

marketing. Could you describe the functions of the global marketing department at Schering?

A. The responsibilities for the global marketing group are several. First of all, their responsibility is to work closely with the research group to provide input as to what the commercial needs are going to be for product development. So, from that aspect, we develop -- we represent all of the subsidiaries from around the world in terms of inputting to the development process what the commercial needs are.

Q. When you say "subsidiaries," could you tell us what's included in that?

A. These are our individual operating units around the world. For example, U.S., we have a subsidiary here in the U.S., but we also have them in France and I think that we have probably a hundred subsidiaries around the world.

Q. Okay, please continue.

A. So, as a part of that process, we would be providing input into the research team working on a product to tell them what the particular attributes a product has to have in order to be successful. And then as a product moves down that development path, we would then develop the marketing concepts behind the product, the positioning -- what we call the

positioning of the product, and then you now start sending that information out to the field, to sort of -- to the subsidiaries as a road map telling them these are activities they should be doing now.

They should begin to understand the market, what type of premarketing activities they should be doing, and then as even the product comes up to market and after market introduction, work with the subsidiaries to assist them in any -- in helping them better understand the product, how to better position the product. So, that was one part of our responsibility.

And the other part of our responsibility in global marketing was evaluating products for potential in-licensing.

Q. Now, does global marketing actually do the marketing other than in the fashion you've just suggested, as backup for the subsidiaries?

A. No. As I said, the role of global marketing is to provide the road map for the subsidiaries, but at the end, it's actually the subsidiaries who actually do the local marketing and selling of the product.

Q. And that includes in the U.S., the U.S. subsidiary does that?

A. Yes.

Q. Now, what was your role in global marketing for the five or so years that you were there?

A. My position was the -- what we called the business unit head, and that meant I was the -- responsible for the cardiovascular and CNS business unit within global marketing, and the exact title was senior director of global marketing, cardiovascular and CNS.

Q. And who was in charge of cardiovascular/CNS within global marketing?

A. That was me.

Q. Now, you've said cardiovascular. What types of products does -- yeah, what types of products would be included in cardiovascular?

A. Products having to do with heart attacks, certainly cholesterol-lowering products. We had a product in development for cholesterol lowering. We had licensed in a product for unstable angina, myocardial infarctions, and we were also looking for other drugs in development for thrombus and other cardiovascular diseases.

Q. In your work in the pharmaceutical industry, have you had experience in cholesterol-reducing drugs?

A. Yes.

Q. And how did you gain such experience?

A. Well, I had some understanding of the cholesterol area through my training as a pharmacist and practicing as a pharmacist, but most of my knowledge and experience really began in April of 1995 when I went to work in the global marketing group, because Schering had in development a cholesterol-lowering agent called ezetimibe.

Q. And what is ezetimibe?

A. Ezetimibe is a unique cholesterol absorption inhibitor that works by inhibiting the absorption of cholesterol through the wall of our gut, which is unique amongst all the products out there used to manage cholesterol, and we believe because of its unique profile, it is going to substantially change the way patients are treated with cholesterol, and it's our belief that it will probably be the biggest product in the company's history.

Q. Do you have sales projections at this point?

A. I don't have the exact numbers, but it's bigger than everything -- anything we've done now, and Claritin does $3 billion. So, it's going to be above $3 billion.

Q. When did you start working on -- I take it this is a product that's still in development?

A. It's in development in the sense that we have

already -- we have filed the NDA. The NDA was filed just at the end of 2001. So, now we are awaiting FDA approval.

Q. When did you start working on ezetimibe?

A. Shortly after joining global marketing, because as I said, the product was in development at that point in time.

Q. And were you working on ezetimibe in 1997?

A. Yes.

Q. And approximately what portion of your time was spent on ezetimibe in 1997?

A. I'd probably say 35-40 percent of my time.

Q. And why so much time?

A. Well, as a product moves down the development path, the need for involvement and input from the commercial group increases, because at that point in time, we have to now start telling the researchers what particular products we want them to compare our product to in clinical product studies, what type of patient population would we like to see the product tested in and what have you.

Q. And so what type of education were you giving yourself about -- to help you with ezetimibe?

A. How you develop that knowledge is several different ways. One way is using what we call

secondary information sources, and this is syndicated studies that somebody else has done that you can read, published literature about the particular category, competitor studies and what have you. There's what we call primary market research, which means this is market research studies that we would conduct to go around the world and interview physicians on what they see as the unmet needs, the future changes in cholesterol management. We would hold advisory panels in which we would get a group of experts together to ask them questions about a particular therapeutic area, and I would also -- myself, for example, I would attend each year two or three major cardiology meetings around the world where they frequently would discuss cholesterol -- the current cholesterol management, future trends in cholesterol, future products that are coming into development for cholesterol.

Q. And did you also meet with individual physicians?

A. Yes, as a part of my job in global marketing, I would go out and visit with our subsidiaries around the world, and actually when I would be visiting the subsidiaries, I would frequently go and visit local opinion leaders, again, to get their feedback as to what they see are the unmet needs in the marketplace.

Q. When you say opinion leaders, are these physicians?

A. Yes, these are usually national experts, in some cases worldwide experts in a particular therapeutic area. In this case it would be cholesterol.

Q. Now, did you study, for example, the size of the cholesterol market?

A. Yes.

Q. And what kinds of things did you look at there?

A. To look at what -- there are resources that one can look at today, probably the most commonly used one is called IMS, which is a database that virtually everybody subscribes to that reports on sales on a given product, breaks it out by geographical area of the country, however you want it broken out. So, that tells you what sales have been to date.

And then in terms of future sales, one looks at a number of different things. Clearly by talking to opinion leaders, you have a clear understanding of what changes are going to take place in, for example, treatment guidelines that national health authorities put out, for example, the NIH here may put out guidelines having to do with cholesterol management, looking at what new products are coming to the market,

that can certainly change the size of the market, because the more players that are in there, the more they raise the awareness to the public, for example, in managing cholesterol. So, you look at future competitors. And again, you just read a lot of different information out there, analysts -- because the analysts -- the Wall Street community looks at the size of the markets, like cholesterol, closely. You can read all different types of syndicated reports, analysts' reports that report on what people believe the trends are going to be of the cholesterol market.

Q. Did you say trends?

A. Trends, yes.

Q. That's into the future?

A. Yes.

Q. And did you, for example, educate yourself about the various drugs that were already on the market?

A. Yes, as a -- as a part of this whole process of understanding the market would be to -- again, through this market research, in talking with physicians, having a very strong understanding of what products physicians are currently using today, what they still see are unmet needs in the marketplace, and what are the thoughts on some of the future products in

development.

Q. What products were on the market in 1997 for treatment of cholesterol?

A. In 1997, and still today, the primary class of drugs that's used in cholesterol is a group of drugs called statins, but there are also other classes of drugs, fibrates, which are mainly used for the triglyceride effects, resins, as well as niacin. Those are the four major classes of drugs that are used for the management of cholesterol.

Q. In global marketing, who was responsible for ezetimibe?

A. I was.

MR. NIELDS: Your Honor, I think I am now about to move into a few in camera documents, which unfortunately means that we need to close the --

JUDGE CHAPPELL: Okay, the public will now need to leave the courtroom. We are getting ready to go into an area of in camera information.

(The in camera testimony continued in Volume 18, Part 2, Pages 4298 through 4305, then resumed as follows.)

BY MR. NIELDS:

Q. Mr. Audibert, during your work on ezetimibe, did you learn about niacin?

A. Yes.

Q. And were you already familiar with niacin before then?

A. Well, again, as I've mentioned before, as a pharmacist, in my training, you learn about various drugs, and obviously as a practical pharmacist, I -- you just know of things and would learn about niacin, but again, the bulk of my knowledge with niacin was really generated through all the work I was doing on ezetimibe.

Q. And what did you learn about niacin insofar as it applied to cholesterol?

A. Well, we had learned that niacin had been a drug that for many years had been known to have a positive effect on various lipid parameters that are important in treating patients with cholesterol, lowers LDL, raises HDL, lowers triglycerides, lowers lipoprotein (a). So, on the one hand it's been shown through some long-term morbidity studies to have a positive effect. In fact, it's incorporated into our treatment guidelines that are put out in this -- for example, in the U.S., we have a thing called the NCEP guidelines, which recommends niacin as one of the agents used to manage patients' cholesterol.

So, again, it's a drug that's been known to be

effective in reducing cholesterol, but at the same time, it does have some limit -- the existing formulations had limitations, and those limitations were the immediate release niacin products tend to cause a high incidence of flushing and itchiness that many patients would not tolerate and therefore would discontinue therapy, and in the past there had been some previously marketed sustained release niacin products that weren't marketed for cholesterol lowering, but they had been on the market, and some of those products had been associated with some fairly high incidences of elevated liver enzyme levels.

Q. Now, did there come a time in 1997 when you focused more specifically on niacin?

A. Yes.

Q. And how did that come about?

A. As a part of the business development activities, as -- from global marketing, as part of this business development team, we were asked to evaluate a product called Niaspan that was being developed by Kos Pharmaceuticals.

Q. And what was the context in which you were being asked to evaluate Niaspan?

A. We were -- we were looking at this as what we called a co-promotion deal, which means that we would

be promoting the product along with Kos.

Q. And what was Kos?

A. Kos was a small pharmaceutical company in Florida, actually the CEO of Kos had been the CEO of Key, Mr. Michael Jaharis, and the goal of Kos was consistent -- he wanted to do with Kos what he had done with Key, which was to take older drugs, which had known efficacy but had some limitations with their existing formulations, and put them into new sustained release formulations that would make the products either improved efficacy, better safety profile, and make them commercially successful in the marketplace.

Q. And did you participate personally in some discussions with Kos regarding this co-promote of Niaspan?

A. Yes, I participated in at least one and perhaps two conference calls with Kos.

Q. What was the stage of development of Niaspan at the time these discussions took place?

A. The stage of development of Niaspan, it was -- they had submitted their NDA in the previous year, so they were actually in the final stages of discussions with the FDA, because Kos had told us they were having labeling discussions with the FDA at that time, and one doesn't have labeling discussions with the FDA for a

product until the medical reviewers have basically signed off on the product, meaning that it's been shown to be safe and effective.

Q. Now, I'd like you to turn to a document in your binder which is SPX 924. It's dated February 11, 1997, and at the bottom of it it says, "Please distribute this material to the CV licensing group for review and discussion at the next meeting," which apparently was 3 -- March 3rd, 1997.

Are you in the CV licensing group?

A. Yes.

Q. And what is this document?

A. This is a document provided to Schering-Plough from Kos that has some overview information on the product, a copy of its proposed labeling, as well as a clinical study on the Niaspan product.

Q. Turning to a page of the proposed labeling, down in the lower right-hand corner you'll see numbers, and this one bears SP 002792, have you got that one?

A. Yes.

Q. There's a chart down at the bottom of that. What's this chart show?

A. This chart reports a summary of the effect of Niaspan alone, Niaspan and HMG-CoA is the more technical term for statins that I talked about before,

so a study that Niaspan had done with a statin, and Niaspan and BAS. BAS is the more technical term for resins, and it shows the effect of Niaspan, Niaspan with a statin, Niaspan with a resin, on various cholesterol parameters during various times during the clinical studies.

Q. Now, you mentioned that you actually personally were involved in one or two discussions with people from Kos?

A. Yes.

Q. I'd like to show you a document that has been marked SPX 18. It bears a title at the top Phone Call, and then it shows contact date, 3/13/97. Do you have that in front of you?

A. Yes.

Q. What is this?

A. This is a summary of the phone conference that took place between myself and some other folks from Schering and two people from Kos.

Q. Is this a summary prepared inside Schering?

A. Yes, this is -- we call this a contact report, and it's usually prepared by the individual who's coordinating the discussions with the other company, in this case it's Karin Gast.

Q. Now, in the second paragraph, it states, "Jim

in particular wanted to know what is the safety profile for Niaspan."

Who is Jim?

A. That's me.

Q. And did you ask about the safety profile of Niaspan during that conversation?

A. Yes.

Q. And what were you told?

A. I was told that the drug had a much better safety profile in terms of the flushing compared to immediate release niacin and I was also told that it had a very low incidence of elevated liver enzymes.

Q. Now, there is a paragraph here that says, "Apparently there was this one study with Dr. McKinney who used sustained release niacin and had his patients averaging five times upper limit of normal for SGOT."

Is SGOT a liver enzyme?

A. Yes.

Q. And was this stated by Kos during this conversation?

A. Yes.

Q. And are you familiar with that study?

A. I'm familiar with that study, and I've actually reviewed that study. I cannot find that study where that claim, averaging five times upper limit of normal.

What I remember from that study is a large percentage of the patients in the study taking the sustained release niacin, I believe it was about 66-67 percent of the patients showed liver enzymes above three times upper limit of normal.

Q. And Kos is telling you that their product shows much lower?

A. Yes.

Q. By the way, is flushing dangerous?

A. No, it just -- it's a condition which patients feel very uncomfortable with, and usually if the patients get enough flushing, they will discontinue the therapy.

Q. Now, toward the bottom of the page, there's a statement, "The NDA was filed 5/6/96. FDA has completed the medical review and they are currently discussing labeling with Kos."

Is that consistent with what you told us earlier that you learned from Kos?

A. Yes.

Q. And completing the medical review means?

A. The fact that the medical review has been completed, again, that means from the -- the FDA has judged the product as being safe and efficacious, now it's just a matter of finalizing what the sponsor --

what the -- the actual labeling would be.

Q. What else do you recall about this conversation with the Kos people?

A. Two other things I remember. One in regard to opportunities for Niaspan outside of the U.S., it was clear that the ex-U.S. business right now was not a priority for Kos, that they wanted to focus on the U.S. business, and second of all, the other part that I remember quite distinctly is that what Kos was asking for from us in terms of support from our sales representatives I thought were irrational and something that was going to be very difficult for us to agree to.

Q. And did you participate -- did you actually talk to them about this?

A. Yes.

Q. And what was the exact subject of your conversation?

A. Well, the issue was is that Kos wanted to have their product, when promoted by our sales representatives, being promoted in what we call the primary position, which means when our sales representative goes into a doctor's office, that's the first product they would discuss. Kos wanted a commitment from us that their product would always be in the primary position, and we tried to explain to Kos

that we could not guarantee that. For example, we have Claritin. In the midst of the allergy season, given the importance of Claritin to the Schering-Plough Company, the sales reps will be detailing Claritin in the primary position.

We did try to explain to them, we can give you enough details in the secondary position that would give you what we call enough noise level in the marketplace, but they -- no, they were very adamant, they wanted guaranteed primary positions.

Q. Now I'd like to show you a document which bears Exhibit Number CX 544. It's dated March 14th, 1997, and I'll ask if you can identify that.

A. Yes, it's a memo I sent out to our subsidiaries asking them some -- for feedback on what they saw as the commercial opportunity for a sustained release -- what they -- some feedback regarding the status of sustained release niacin in their country and what they saw as the potential opportunity for a sustained release niacin in their particular country.

Q. What was the purpose of -- and was this actually sent?

A. Yes.

Q. And what was the purpose of sending it?

A. Again, based on my previous discussion with

Kos, the fact that there was the possibility that we could get the license to the product ex-U.S., to get some feedback from the subsidiaries what value they saw in the product.

Q. And do you recall if you received responses?

A. I don't recall receiving any responses.

Q. Now, did you expect that you would get useful responses?

A. No. Based on my experience, it was not uncommon for us to do this, but especially in areas where the subsidiaries had no expertise in the given therapeutic area, say in this case cholesterol, it was frequent that we got no responses, because the subsidiaries had no real basis to provide any meaningful input.

Q. Did Schering have any cholesterol-reducing products on the market in -- overseas?

A. No.

Q. Or here?

A. No.

Q. Now, Mr. Audibert, why was Schering interested in Niaspan?

A. Well, I think the -- several reasons. I mean, the first reason is it was a late stage product. I mean, we're always looking for products that are close

to the market, because they will obviously give some revenues, you know, very quickly. So, that's one thing, it looked like an interesting product, near-term product coming to market, so that in itself I think raised some interest.

Perhaps more importantly, the fact that we were working in the cholesterol market, in terms of development of ezetimibe, and the fact that we eventually would be launching ezetimibe into a very, very competitive cholesterol marketplace that's literally ruled by the Goliaths of the pharmaceutical industry, whether it's Pfizer, Lambert, Merck, BMS, I mean huge companies which are a huge amount of resources and behind the product, it was -- you know, I saw this as a real opportunity, as I think Ray did, to get into the cholesterol-lowering market before ezetimibe in terms of getting us in there, getting us to better understand the marketplace, and not only just us, but the subsidiaries get in there with a product and sort of earn your bumps and bruises with a product before we get to ezetimibe.

Q. You mentioned Ray in your last answer. Who is Ray?

A. Oh, Ray Russo was my counterpart on the U.S. side. He was the marketing director for Key

Pharmaceuticals, which was responsible for cardiovascular products.

Q. And was he also working on this Kos product?

A. Yes.

Q. I'd like you now to turn to a document bearing SPX 21. It's dated March 26, 1997.

Can you identify it?

A. Yes, this is actually a document from Ray Russo, the individual we just discussed, sent out to several people within Schering-Plough talking about the opportunity for the Niaspan product and some of the issues that he wanted to have addressed as a part of the assessment.

Q. Now, about two-thirds of the way down, there's a paragraph beginning with the number 1 that says, "SGP/Key," what's SGP?

A. That's Schering-Plough.

Q. Okay, "SGP/Key would need guarantees on active participation and input into promotional and strategic efforts for the brand," and the brand here is Niaspan?

A. Yes.

Q. Then it goes on, "This is essential to obtain the early strategic leverage and market expertise that would allow us to strategically bridge to our only 58235 compound."

Do you see that?

A. Yes.

Q. Is the 58235 compound ezetimibe?

A. That's ezetimibe.

Q. And did you have conversations with Mr. Russo about this concept of using Niaspan strategically to -- to strategically bridge to ezetimibe?

A. Yes.

Q. And can you describe those conversations?

A. I can't describe a given conversation, but Ray and I would converse, you know, many times on a day, and we clearly shared the vision of growing Schering's cardiovascular portfolio and the importance of developing strategies to make us more successful with ezetimibe, which our earlier market entry with another cholesterol absorption -- another cholesterol product would be extremely important for us.

Q. Did there come a time when you personally stopped working on Niaspan?

A. Sometime in probably late March, early April, I don't know exactly when, but somewhere along that time, I essentially disconnected from the process, mainly --

Q. Why was that?

A. Because based on that one discussion that I had with Kos, I saw it was unlikely that we would come to

some type of agreement with them, because they were just being totally irrational in what they expected for the product.

Q. Mr. Audibert, did there come a time when you looked at another sustained release niacin product?

A. Yes.

Q. And when was that?

A. That was in June of 1997 when my boss, Tom Lauda, asked me to do a commercial assessment of a product called Niacor-SR.

Q. And whose product was that?

A. That was a sustained release niacin product from Upsher-Smith.

Q. And what was the purpose for doing this assessment as Mr. Lauda described it?

A. Mr. Lauda indicated that we had the opportunity to obtain the license for the product ex-U.S., Canada, Mexico, and then to develop a commercial assessment of the product based on the information he provided to me.

Q. Ex-U.S., Canada, Mexico, I take it means outside of -- in territories outside of the United States, Canada and Mexico?

A. Yes.

Q. Did -- do you recall if Mr. Lauda communicated to you that -- any time frame for getting this

assessment done?

A. I don't remember Tom telling me any specific time frame, but having done a number of these activities for Tom, he usually wanted it done quickly.

Q. Did Mr. Lauda mention anything about a patent litigation or a settlement or anything like that?

A. No.

Q. Do you recall if Mr. Lauda mentioned any amount of money that was being asked for the license rights by Upsher?

A. No.

Q. Now, you mentioned some materials. Did you receive some materials to do this assessment based on?

A. Yes.

Q. And what materials did you receive?

A. I received a packet of information that was from Upsher-Smith that was a -- contained information from the clinical studies as well as some synopsis of two protocols.

Q. And what is a protocol?

A. A protocol is the design of the study. Basically the protocol outlines exactly how the study's going to be conducted, what's the objective, what the drugs are going to be used, how it's going to be run, how often patients are going to be tested and what have

you, and the synopsis of that is just basically a summary of that particular study.

Q. And were these protocols for studies that had been done or studies that were to be done?

A. No, I believe these studies were what we called -- these studies were what we called III-B studies, which means they're studies that are going to be done not for the initial registration of the product but to get some further change in the labeling.

Q. So, you described an information packet that had data from clinical studies. I take it those were different studies than had actually been done.

A. Yes, those are the studies that were going to be registration studies.

Q. The ones that were in the packet of information?

A. Yes.

Q. That had actually results from them?

A. Yes.

Q. Now, I'd like you to turn to a document that's marked CX 1042 and ask you if you could tell us what that is.

A. This is the information packet that Upsher-Smith had provided to us that contained the information from the clinical studies about the

products, about Niacor-SR.

Q. And then I'd like you to look at SPX 71 and SPX 4 and ask you to tell us what those are.

A. These are the protocol synopsis that I just discussed about two studies they were -- that Upsher-Smith was planning to conduct with Niacor-SR.

Q. And what did those protocols cover?

A. The -- one study -- one protocol looked at the product being used in combination with a statin, and the other protocol covered using the drug dosed in the evening.

Q. Now, did you do a commercial assessment of Niacor-SR for sale outside the United States, Canada and Mexico?

A. Yes.

Q. Can you describe for us your approach to doing that assessment?

A. Okay, the approach I used here was consistent with the approach I would use in -- when I would -- was asked to do other assessments, and so the first thing I would look at when I was asked to do an assessment in this case, I would look at the therapeutic area and is it an area that I know somewhat about, I know a lot about, a little about, and clearly in the case of cholesterol, because of all the work I'd been doing for

ezetimibe, it's an area that I knew extremely well because of all of my ongoing activities.

So, the next step in the process is is there a proof of principle in place regarding the use of this particular drug in this particular indication, and again, in the case of niacin, as I mentioned several times in the past, niacin has long been established as a drug that's been shown to have a positive effect on various lipid parameters. It's a part of the NCEP guidelines, and I also knew from the Kos discussions that the FDA was on the verge of approving a sustained release niacin product for hypercholesterolemia. So, the question is there proof of principle in place that says does niacin work for cholesterol, the answer is absolutely, yes, that's well established.

Then the third question one would ask themselves is is there an unmet need in the marketplace? Is this product addressing an unmet need? And as I mentioned before, while niacin has been shown to have a positive effect on various lipid parameters, its side effect profile, both in terms of the flushing and parietis, the itching associated with the immediate release products, along with the high incidence of elevated liver enzymes in the previously marketed sustained release niacin products, would lend one to

conclude that if one had a sustained release niacin that had a much better safety profile in the area of both flushing and itching as well as elevated liver enzymes, that product could be a commercially successful product in the marketplace.

Then the last thing then I would do is I would actually look at what is the -- look at the information that had been provided to me, in this case by Upsher-Smith.

Q. Was that to determine whether, indeed, they had been able to develop an SR niacin that met the safety parameters you've just described?

A. Yes.

Q. Now, you've indicated there was already proof of principle in the sense that niacin works to help with cholesterol. In your review of the actual clinical results from Niacor trials, was that confirmed or not?

A. Yes, the study showed that Niacor did produce a 15 percent reduction in LDL, which is the regulatory hurdle for getting approval for a cholesterol-lowering agent.

Q. And what, if anything, did the clinical data show about flushing?

A. Well, the data showed that the -- there was a

significant lower incidence of flushing with patients taking Niacor versus the patients taking immediate release niacin product.

Q. You said versus immediate release?

A. Immediate release niacin, exactly.

Q. And if you could turn again to CX 1042 to a page that bears a Bates stamp number in the lower right-hand corner of SP 1600089. Do you have that in front of you?

A. Yes.

Q. And is the information regarding flushing that you just referred to on that page?

A. Yes.

Q. Would you point to it?

A. Yes, on the top of that page, 00089, there's a chart that shows the average number of occurrences of flushing of the four different patient groups in this particular clinical study, and as you can see, under column A, there was 131 average number of occurrences in -- and A is the immediate release product, and B, C and D are three different dosages of Niacor-SR. So, one can see there was approximately a four-fold reduction in the incidence of flushing with the Niacor product versus the immediate release niacin tablet.

Q. I've put that up on the ELMO, and is that the

part of the document that you were just testifying about?

A. Yes.

Q. And does it -- just so we understand this chart, does the column A refer to the immediate release flushing results?

A. Yes, column A is the immediate release niacin product, and B, C and D are three different dosages of the Niacor-SR product.

Q. And the four-fold reduction is shown in the numbers on the bottom part of this chart?

A. Yes, you see 131 was the average number of occurrences per patient with the immediate release, and you see it's 26, 32 and 38, I believe it is there, it's fuzzy, but you can see a substantially lower incidence per patient with the sustained release product versus the immediate release product.

Q. Now, what did the clinical data package show about elevated liver enzymes?

A. What the data showed, that there was a low incidence of patients who experienced successive increase in liver enzymes that were above three times upper limit of normal, and the data also showed that even those patients who did have elevated liver enzymes, the elevated enzyme -- the liver enzymes

reversed back to normal after discontinuation of the drug.

Q. And what was the incidence of elevated liver enzymes that you focused on?

A. I believe it was the successive -- the percentage of patients who had successive increases in their upper -- of liver enzymes that was greater than three times upper limit of normal.

Q. And what percentage was that?

A. I believe it was 4 percent that -- of patients on the two high doses of Niacor-SR showed.

Q. And why did you focus on a measurement three times upper limit of normal?

A. Because that is the level of elevated -- elevation of liver enzymes that clinicians as well as regulatory reviewers look at. Below less than three times upper limit of normal -- below three times upper limit of normal, most people would say is not really clinically significant, because we all have normal fluctuations in our liver enzymes as a part of our daily activity.

Q. I'd like you to turn to a page of CX 1042 that bears Bates stamp number SP 1600092 and ask you whether on that page you see the results of elevated liver enzyme levels that you just testified about.

A. Yes, the chart on the bottom of that page, which is consistent with the chart that you have now up on the screen, one can see the far right-hand column, and this talks about two successive notable elevations, and again, if one goes to the title of the slide, notable is defined as equal to or greater than three times upper limit of normal for liver enzymes. So, if one looks at the group C and group D, these are two groups of patients who are on Niacor-SR, these particular patients exhibited a 4 percent incidence, and this is -- 4 percent is actually consistent with the type of elevation of liver enzymes that is seen with, for example, statins.

Q. Okay. And you mentioned -- you mentioned that the study -- the data that you got on Niacor-SR also showed that after people were taken off the drug, their levels returned to normal, and I'd like you it turn to page 1600093 of Exhibit CX 1042 and ask if that page contains the support for what you just told us about the levels returning to normal.

A. Yes, at the bottom of that page, there's a chart, which again is now the chart that you have up on the screen, that actually talks about what happens with those patients who did have elevation of liver enzyme -- elevated liver enzymes, and you can see that

they did return to normal when the dose was discontinued or even lowered.

Q. And was that true of everyone for whom they were able to get measurements?

A. Yes.

Q. Now, Mr. Audibert, why is that important?

A. Well, for two reasons. Most importantly, it tells us that the side -- that the effect in terms of elevation of liver enzymes is a transient effect and it's not causing permanent liver damage, because that's something that you're most concerned about, if one were to see elevation of liver enzymes, is it reversible or irreversible, and this data clearly showed that it was reversible. That's the most important part of it.

Q. And in the real world, how do doctors know to take a patient off a drug if the drug raises their liver enzyme levels?

A. The physician would know that by taking periodic blood samples, and given the fact that virtually every cholesterol-lowering agent can cause some increase in liver enzymes, when patients are placed on a cholesterol-lowering product, the physicians will then periodically take a blood sample, look at the patient's liver enzymes, and if they're liver enzymes are raised, then the physician will

either decrease the dose of that particular product or discontinue the therapy.

Q. Now, what conclusions did you draw from the data in CX 1042, the clinical results that Upsher had sent, on the question of whether Niacor-SR, in fact, met unmet needs out there in the cholesterol marketplace?

A. Well, again, as I discussed, the issue with niacin is not whether it worked but can it be in a formulation that patients will tolerate, and what this data showed me, that that drug did have efficacy and met the regulatory hurdle for efficacy, the 15 percent LDL lowering, but also showed that the incidence of flushing and headaches was significantly lower than immediate release niacin and also showed a low incidence of elevation in liver enzymes. So, put all together, this told me this is a product that was registerable and was able to address an unmet need in the marketplace.

Q. And how did the -- again, how did the liver enzyme levels for Niacor-SR compare to the sustained release niacin product you testified about earlier that you discussed with Kos?

A. Well, based on what Kos told me, they would appear to have a lower incidence of --

Q. No, I'm sorry, I'm talking about the old sustained release niacin that had the --

A. Oh, I'm sorry. Clearly, as I mentioned before, the previously tested sustained release niacin products, prior to the Kos product, I believe two-thirds of the patients had more than three times upper limit of normal of their liver enzymes, where this was 4 percent. So, it was a huge reduction in the incidence.

Q. What did you do next in doing your commercial assessment?

A. Well, now that I had looked at this -- analyzed this data and came to the conclusion that the product was registerable in terms of it was efficacious, it had a side effect profile that I think addressed an unmet need in the marketplace, the next thing I would do then is go about in constructing a sales forecast, and the way I would do that is the first thing I would do is put together what I believed the cholesterol-lowering market was going to be for the next -- whatever the time frame would be, I think in this case I looked at ten years, if I'm not mistaken. Again, given all the work I had been doing with ezetimibe, I had been spending a large amount of time forecasting what the market size was going to be in different parts of the

world over the next ten period -- ten-year period, and the reason -- this is probably the most important, because at the end of the day, your sales forecast in many ways is going to be driven not only on the product attributes but clearly what the size of the market is, and with the cholesterol market, it was going -- it was growing very, very strongly, and in all of my own analysis, but certainly what an analysts would give you, had predicted very, very strong increases in the cholesterol market over the next ten-year period.

Q. Okay. So, what do you do after looking at the size of the cholesterol market?

A. Well, once -- you then look at what one projects to be the market size, the next thing you have to look at is how -- you know, look at the product profile, how would you envision positioning this product, how would you envision pricing this product, and that will ultimately get you to what you believe your market share will be.

What I mean -- in terms of positioning, what I saw with the Niacor-SR product, that means that the product could be used as a monotherapy, i.e., by itself, or it could be used in combination with a statin, because again, as I know, statins are products that are commonly used, as we discussed before,

physicians in Europe often use multiple drugs to treat cholesterol. So, my position would be it is a product that can be used by itself or in combination with a statin.

The next step is to look at what would I envision the price of the product to be. Now, knowing that there are very potent products out there, such as the statins, I think one had to be realistic in terms of if this product in itself has a 15 -- you know, 16 percent LDL lowering and you have products out there that -- Lipitor, that have, you know, high 30 percent LDL lowering with the starting dose, it's unrealistic to think that I am going to get the price that's comparable to Lipitor. I envisioned that I would get a price of approximately half of what the Lipitor would be priced at.

And again, I saw this also helped in the positioning of the product, because I knew from my experience in talking to cardiologists and even health payers in various parts of the world, there was a major issue with a lot of countries that they recognized that their patients in the countries should be treated for the cholesterol, but if they put everybody on a statin who should be on a statin in their country, they would literally run out of money in the health system,

because keep in mind, in most of these countries, the Government runs the health system. So, there was a real opportunity I saw for a product that had what I would define as modest efficacy, but to be a lower priced product that, again, health authorities could now provide their populace as a way of at least managing their cholesterol.

So, based on the positioning, what I saw as a profile, what I saw as a pricing, I would then estimate what I see is a reasonable market share based on all those factors, and then once you have your market size and once you estimate what you believe your market share will be, it's just a means of math and just multiplying the market share times the market size, and that will provide you with the sales projection in a given year.

Q. Okay, I'd like you to turn to a document that's marked SPX 2.

A. Two?

Q. Yes.

A. I'm sorry, okay.

Q. Do you have that in front of you?

A. Yes.

Q. It's got a cover sheet dated June 17, 1997. Can you tell us what this document is?

A. This is -- the market attached to the cover sheet -- excuse me, the document attached to the cover sheet is my commercial assessment for the Niacor-SR product.

Q. And I'd like you to turn to the back of the document. You'll find -- I think it's the second to last page of the document, it's titled Table I, and at the top it says, "Worldwide (ex-U.S., Mexico, Canada) Cholesterol-Lowering Market," and then it has, "(billions of dollars)."

First of all, tell us what this page is.

A. This page is what I believe the -- what I was projecting the cholesterol market, again, in the territories being worldwide with the exception of U.S., Mexico and Canada, could be in the years 1996 through 2007, and those sales numbers are in billions of dollars. And then below that is the percent change from the previous year of the market size.

Q. Okay, so you've got a line on this document, I've now put it up on the ELMO, that says, "Sales," and the numbers that go along under the years, those are the total cholesterol market sales measured in billions?

A. Billions, yes, and that -- in the territory, which again is ex-U.S., Mexico and Canada.

Q. Okay. And then turning to Table II, which is the next document, can you tell us what that page shows?

A. This now is my best judgment of what I believe the Niacor-SR sales would be from 1999 to 2008, and under Sales, you can -- those figures are -- those would be product sales in millions of dollars for each year, and below that is the market share that those sales represent. So, I was essentially -- for example, 1999, I projected a 0.75 percent market share, I would multiply that 0.75 times the sales -- the category sales that we had on the previous chart, and that comes up with $45 million.

Q. And then you've done the same kind of calculation, estimating market share and then multiplying that times the total market to give you the dollar sales for Niacor-SR?

A. Exactly, the sales result from multiplying the market share times the market size, and that results in market sales -- in product sales.

Q. Now, did you make any assumptions about whether Niacor-SR would be approved or approvable in the various places that Schering would sell it?

A. Yes, I approved that -- I assumed that the product was going to be approved in most major markets.

Q. And why is that?

A. Because I saw from the information that the product had met the regulatory approval for a cholesterol-lowering agent, which was 15 percent LDL, and I also believe that the side effect profile of the product was more than satisfactory to get a regulatory approval.

Q. Now, did you make some other assumptions that went into the market share and sales projection table that is called Table II?

A. Yes, and those assumptions are listed as bullet points underneath the sales forecast in Table II.

Q. Okay, I'd like to go over those with you. The first -- let me see if I can get this a little better an the ELMO. It may not work, but I'll just give it a try.

There's a heading Assumptions/Rationale, and then the first bullet says, "Dossiers approved late 1998."

What was the basis for that assumption?

A. The basis for that is based on the information that Upsher-Smith had provided us, they were planning to do their NDA filing at the end of 1997. We would use their NDA as the basis of putting together our international filing for Niacor-SR, and we expected

that by using their NDA as the basis, to make the necessary modifications and plan to submit the dossier at the end of 1997, and assuming a 12-month review time, which is the time that we normally use to assume for approval, that would put us at approval in late 1998.

Q. And when did you anticipate that you would get the sort of data from Upsher-Smith that was going to go into their NDA filing in order to start preparing the filings outside of the U.S.?

A. The key piece of information that I anticipated us getting from Upsher-Smith was based on the time lines they had provided us in October of 1997, they would have what they called the ISS and ISE, which is the integrated summary of safety, integrated summary of efficacy, and we would be using this information to build our international dossier.

Q. And if you just take a look at -- back at CX -- and I am going to put this up on the ELMO, so you don't need to actually turn to it, Mr. Audibert -- back to CX 1042 at a page that's Bates stamp numbered SP 1600079, and I think you've testified that CX 1042 was the data package that you received from Upsher-Smith, and I direct your attention to that part of the document that's headed Niacor-SR Clinical Program,

Status of U.S. Regulatory Submission, and the second to the bottom line says, "ISS/ISE, Final Report, October 1997."

A. Yes, that's what I just discussed. That's the ISS/ISE that he would be using as the platform to build our international dossier.

Q. Okay. Now I'd like to move to the next assumption, which says, "Reimbursed in most major markets."

What was the basis for that assumption?

A. Well, as I mentioned before, I believe that not only the drug met the regulatory approval hurdle for cholesterol lowering, but I believed there was a real opportunity to position this product to health authorities as being a product that would allow them to treat a larger number of their populace who have elevated cholesterol, and again, the thing there was pricing this at a fairly low price. I saw it as a real opportunity that the health authorities would actually want to reimburse it, because they would want to have more of their patients in the country treated for cholesterol.

Q. All right, then the next bullet reads -- I think we may run out of space here to show it on the ELMO, so I am just going to read it -- "Niacor is the

only SR niacin approved for hypercholesterolemia -- both as monotherapy and in combination with statin."

What was the basis for that assumption?

A. Well, actually, one has to look at that bullet point and the one below that, because I -- the third bullet point is the only SR, I assumed that for three years we would be the only product approved for -- only sustained release niacin product approved for hypercholesterolemia both as a monotherapy and in combination with statin. I assumed that we would be getting the statin claim because of the protocol synopsis that I had seen that Kos -- excuse me, that Upsher-Smith was going to be developing and conducting. Again, the fact that niacin had been recommended in various guidelines, I knew that Niaspan had done a program with statins. So, I assumed that we would -- there was going to be sufficient data to get that claim, both as monotherapy and in combination with a statin.

But then if you go to the next point down, I also assumed that we would not be alone in the market for too, too long. Within three years, I anticipated Kos or somebody else would come into the market with a similar product.

Q. Okay. Now, first of all, you say you assumed

that Kos or somebody else could come on the market with a similar product. Did that mean that you did not assume that Upsher would be able to block anyone with a patent, for example?

A. Yes, I assumed that there was no patent protection for the product.

Q. And why did you assume that Kos, for example, wouldn't come in before 2002?

A. Based on my discussions with Kos, that it was clear that they were focusing on the U.S., I think they were trying to do an IPO. It's just ex-U.S. was not a focus of theirs.

Q. Now, going back to the second part of this assumption, that it would be approved not only as monotherapy but as combination with a statin, I want to make sure the record is clear as to why you believed that Niacor could at least eventually be approved for use in combination with a statin.

A. Well, several reasons. First of all, niacin is used in practice -- in 1997, physicians would be using niacin to manage patients' cholesterol, albeit in a very low percentage because of the side effects of the existing niacin formulations, but there had been numerous literature talking -- discussing the use of niacin in conjunction with other cholesterol-lowering

agents. As I mentioned, the NCEP guidelines discusses the use of Niaspan -- excuse me, of niacin in combination with several different cholesterol-lowering agents, including the statin. And Upsher-Smith had -- was planning to do a study with Niacor in combination with a statin, and it was just not that difficult to conduct these types of studies. You would take patients, and you would give them Niacor, give them a statin, give them both, look at the effect. And like I said, Niaspan had already done that work and shown that one could effectively and safely use the combination of the two drugs.

JUDGE CHAPPELL: Mr. Nields, let me know when you finish this line of questioning.

MR. NIELDS: Very well, Your Honor. I think I'm maybe five or ten minutes away from a good breaking point.

JUDGE CHAPPELL: Okay.

BY MR. NIELDS:

Q. The next assumption is that the product would be priced approximately 50% to atorvastatin (based on daily cost).

What was the basis for that assumption?

A. The basis for that, atorvastatin is the generic name for Lipitor, which is the -- had been on the

market just a little bit, but it clearly was going to be the market leader given its particular profile. As I mentioned before, Lipitor provides a 39 percent LDL lowering with its 10 milligram starting dose. Again, when I look at the profile of Niacor-SR, when I look at its effect on LDL, I think it was reasonable to expect that a health authority would provide me a price that's somewhere in the area of 50 percent that of atorvastatin.

Q. Now, the next assumption is that the side effect profile of Niacor-SR doesn't significantly change.

What was the basis for that?

A. There was no reason to think it would change, so again, you know, my assessment was based on the clinical information provided in the packet, and I wouldn't expect it to change, but I just wanted to make that point, that all my assumptions were based on having this particular profile.

Q. Now, finally, it says -- and I don't know whether this is an assumption, it looks like an asterisk rather than a bullet, but it says, "Sales and market are worldwide (except the U.S., Canada, Mexico)."

My question to you is, did you assume that

Schering would market Niacor-SR in Japan?

A. No.

Q. And does that mean that your numbers are therefore off?

A. No, I would take those -- those numbers would be taken in my overall market share projection.

Q. So, you had already taken into account the fact that Schering wasn't going to be marketing in Japan?

A. Yes.

Q. Now, Mr. Audibert, did you consult anyone in doing your evaluation of Niacor-SR?

A. No.

Q. And why not?

A. Because I saw this as a very straightforward assessment. It was a -- as I mentioned before, it's a product with a known proof of concept in place, the fact that it's been -- niacin's been shown to work, I felt that I had the knowledge and the expertise to look at the product profile, my knowledge of the market size, and I just think that what you saw there was not what -- not anything surprising. You saw the efficacy profile that's been consistent with niacin; you saw a side effect profile that's improved, and not surprising. In other words, it was very straightforward.

Q. Now, in doing commercial assessments, do you frequently consult people outside global marketing?

A. Yes.

Q. And what -- who would you -- who would be a person or a division that you would consult in the ordinary course?

A. Probably the group that I would contact and discuss most of the time would be the individuals within the Schering-Plough Research Institute, because that would involve regulatory issues, clinical issues, potential toxicology issues, but virtually all of my activities doing commercial assessments were done with new chemical entities, which in themselves raise a whole set of issues that, again, weren't the issues here. This was essentially an old drug in an improved delivery system.

Q. And if you had seen a need to consult here, would you have done so?

A. Absolutely.

Q. Now, I'd like you to look at a document that bears SPX 6.

A. Six.

Q. It is a document -- it has a cover sheet bearing the date June 17th, and my question is, what is this document?

A. This is what we call a profit and loss analysis for the product. Essentially what this shows is what -- using my sales forecast that was on the previous page, using a cost of goods, and we normally would use 10 percent cost of goods in doing these projections, what I estimated the selling/promotional cost to be in any given year, and again, I knew that because I had been doing some work with ezetimibe. So, essentially, if you start off with -- and if you look, for example, 1999, you start off with $40 million -- $45 million in sales, I estimated a 10 percent cost of goods, which would be $4.5 million. I estimated the promotional/selling cost to be $13.5 million. So, basically if you start off with 45 and you take away 4.5 and 13.5, that ends you up with a net profitability of $27 million.

Q. Now, I take it this doesn't include any royalties that might -- that might be included in any deal?

A. That's correct.

Q. And that's because you didn't know what the terms of any deal might be?

A. That's correct.

Q. Now, so, we have two documents that you produced. I take it this one that you've just

testified about and then your report that you mentioned earlier, which is SPX 2, whom did you deliver these to?

A. I provided them to Mr. Lauda, both of them.

Q. And did you discuss them with Mr. Lauda?

A. I don't recollect a specific conversation, but I'm sure when I was done I sat down and reviewed it with Mr. Lauda.

MR. NIELDS: Your Honor, this is a good time to break.

JUDGE CHAPPELL: Okay, let's break. We will be in recess until 11:35.

(A brief recess was taken.)

JUDGE CHAPPELL: Mr. Nields, you may proceed.

MR. NIELDS: Thank you, Your Honor.

BY MR. NIELDS:

Q. Mr. Audibert, did you have any further responsibilities for the Niacor-SR product after your evaluation?

A. Yes, after the agreement had been signed, I was appointed to be responsible for coordinating the efforts with our regulatory and clinical people to make sure that the dossier for international filing were put together and filed.

Q. And was there a plan of action, a general plan of action, to deal with that part of the job?

A. Yes, the overall concept, as I mentioned before, is that we would be using the Upsher-Smith NDA as the basis of our filing, because this is something we frequently did, and the first real piece of information we expected to have were the ISS and ISE, which based on the information that they had provided me was scheduled to be delivered in October. So, after we signed the deal, there wasn't really anything we could do at that very given time.

Q. And again, I think you've said this, but I'm just not certain it's in the record, what is an ISS and what is an ISE?

A. ISS is -- you take all of your clinical studies that have been done with the product, and you put together two important documents, one that's called the ISS, which is integrated summary of safety, which discusses the -- all the safe aspects of the product from all the various studies you've done, and the other part of that is the integrated summary of efficacy, which again is a summary of all the efficacy data from the product -- of the product from all of the clinical studies that you've done.

Q. Now, you said there wasn't much to do before you got the ISS and ISE. Did you take some steps in preparation for that?

A. Yes, I undertook several steps. One is I notified people who were going to be involved in the process that this was going to be taking place just to make -- put them on notice that we were going to be needing their effort later on in the year to put together these documents, and also I tried to arrange a trip to Upsher-Smith with the head of our European regulatory group to start looking at some documents just to see what type of format they were in so he could familiarize himself with what type of information would the information be in.

Q. And who was the head of the European regulatory group?

A. His name is Dr. Jean-Pierre Osselaere.

Q. And where does he live?

A. He's in Belgium, in Brussels.

Q. And you said you tried to set up a meeting with him and that was with the people at Upsher?

A. Yes.

Q. And did that work?

A. No. Unfortunately, the time at which Dr. Osselaere was going to be available to come to the States in mid-September, at that point in time, there was not adequate information that Upsher-Smith could share with us at that point in time that would make the

trip worthwhile.

Q. And did you get the ISS and the ISE in October?

A. No.

Q. And why not?

A. Based on the discussions we had had with Upsher-Smith, they were -- there were delays in their program, in putting together the documents.

Q. Is that kind of delay in getting clinical trial results written up and organized, is that abnormal in the pharmaceutical industry?

A. No, unfortunately, it's quite common.

Q. Did anything of relevance to the Niacor-SR project occur shortly after October?

A. Yes, in November of that year, Kos reported its first quarterly sales of Niaspan, and their sales results were quite low. I don't remember the exact number, but they were very low. I think this was very surprising to us and very surprising to Kos and I think very surprising and disappointing to the stock community, because the Kos product took a major hit.

Q. When you say the Kos product --

A. Excuse me, the stock price of the Kos product -- the Kos price or the price of Kos stock took a major hit.

Q. Why is that -- why was Kos' performance in the

marketplace relevant to the Niacor-SR project?

A. Well, I think that the relevance is the fact that it provided a real world opportunity to test the market -- the product in the market and a real life situation. So, you could actually see how is the product being received by physicians, by how they were doing, and it certainly raised the question of whether a sustained release niacin product could be as successful as we originally thought based on at least the first quarter sales.

Q. Now, what was done by Schering after you learned that Kos had done poorly in the marketplace?

A. Well, there had been discussions with Upsher-Smith. We still awaited the arrival of the clinical studies, the ISS/ISE. And then eventually, later on in 1998, we were notified that Upsher-Smith was abandoning their NDA for the product, and eventually we abandoned our activities around the product also.

Q. For what reason?

A. Well, for several reasons. First of all, the Kos product continued to do poorly in the marketplace. So, right out -- right up front, it told us that perhaps marketing a sustained release niacin product into the marketplace was going to be more difficult

than we had anticipated.

Second of all, the fact that Niaspan had not done well in the U.S. also had some implications for Niacor, because it is very helpful to have a product first do well in the U.S., because a lot of European physicians read the U.S. literature, they attend U.S. meetings, they follow what goes on in the U.S. in many ways. So, if Niaspan had been more successful here, I think it would have made our job easier in Europe.

And thirdly, the fact that Upsher-Smith was abandoning their activities in the NDA meant that there was going to be a lot more requirements from our end in terms of resources to put together our international dossier than we originally anticipated, because as I mentioned before, we were planning to take their NDA, make the necessary -- reformat it and submit it.

And lastly, it was going to be much later than we originally anticipated.

Q. Now, I'd like you to turn to a document which is in your binder as SPX 7 and ask you if you can -- just so the record is clear, I'm now going back over with you the things that were done after the agreement was signed.

A. Okay.

Q. And I'd like you to turn to SPX 7. It's a

document dated July 2nd, 1997, and it is from Ray Kapur to Thomas Lauda. Do you have that in front of you?

A. Yes.

Q. What is that document?

A. This is a memo to my boss, Tom Lauda, from Ray Kapur indicating that he was expecting global marketing to be responsible for making sure the product was being developed and registered and also asked that the project leader keep him updated on a quarterly basis of what's going on with the development of the product.

Q. And who was the project leader?

A. That ended up being me.

Q. And in the upper right-hand corner of this document, there's some handwriting that says, "To Jim Audibert, please see me urgently," and is that Tom?

A. Yes, that's my boss, Tom Lauda.

Q. That's Tom Lauda's handwriting?

A. Yes.

Q. And he's sending a message to you to come talk to him about this?

A. About this memo, that's correct.

Q. Okay. Now, I'd like you to turn to a document that bears Exhibit Number SPX 8. It's also dated July 2nd. Do you have that in front of you?

A. Yes.

Q. And what is this?

A. This is a memo from Mr. Kapur to Mr. Cesan indicating what products that Mr. Kapur was going to be developing by Warrick and just restating the fact that he was expecting global marketing to be responsible for making sure that the product gets registered as well as, you know, making sure it's going to be marketed.

Q. And that's stated down at the bottom paragraph in the typed part of the document?

A. Yes, the part that says, "International registration and marketing of the principal product, Niacor-SR, will be the responsibility of Global Marketing."

Q. And then at the bottom of that document, there is some handwritten, again it says, "Jim Audibert," and then there's a message. Whose handwriting is that?

A. I believe that's my boss, Tom Lauda's.

Q. And he's saying, "Did you see the letter on Upsher-Smith Niacor-SR? We need to put Carolyn on this and get a development program."

A. Yes.

Q. That was his message to you at the time?

A. Yes.

Q. Now I'd like you to turn to a document bearing Exhibit Number SPX 9. It's dated July 16, 1997. It

says it's from R. Kapur, that's Ray Kapur?

A. Yes.

Q. To Mr. Ian Troup of Upsher-Smith, and it shows a copy to you.

A. Yes.

Q. What is this document?

A. This is a document from Mr. Kapur to Ian Troup, and they talk about trying to set up a GMP visit for some of the people from our quality assurance at Schering-Plough, but from -- more from my aspect, it says, "I have also given --" Ray has given me Mark Halvorsen's name, and this is an individual who was a vice president at Upsher-Smith, for a person that I should contact in terms of scheduling a visit out to Upsher-Smith to discuss the Niacor-SR submission.

Q. And did you have conversations after that date with Mark Halvorsen?

A. Yes.

Q. For that purpose?

A. Yes.

Q. And other purposes?

A. Yes.

Q. Now I'd like to show you a document -- I'd like you to turn to a document that bears SPX 241. Do you see that?

A. Yes.

Q. It is a document that bears the date August 14, 1997. It says, "From, Jim Audibert, To, Mark Halvorsen," and what is this document?

A. It's a follow-up from a -- it's a note to Mr. Halvorsen as a follow-up to recent phone discussions we had had asking that I wanted to arrange a meeting for the middle of September to bring Dr. Osselaere out to Upsher-Smith to look at what data they have.

Q. And does it cover anything else other than bringing Mr. -- I take it -- it doesn't mention Mr. Osselaere's name, but it refers to the head of European regulatory?

A. Yes, that's -- that's --

Q. That's Mr. Osselaere?

A. -- that's Dr. Osselaere, he's referred to as our head of European regulatory.

Q. It also says, "I would like to arrange a meeting at Upsher-Smith for the week of September 15th so that our regulatory and clinical people can meet with you to review the Niacor-SR dossier and discuss filing strategies."

Who were you trying to get together in that sentence?

A. Well, I would be getting together somebody from

our clinical research group, I'm not sure at that point in time who exactly that individual would be, but clearly somebody from our clinical research group, along with Dr. Osselaere, to go out and visit Upsher-Smith.

Q. Now I'd like you to turn to a document that bears Exhibit Number CX 1092. It bears the date August 15, 1997. Do you have that in front of you?

A. Yes.

Q. And this is from a Margaret Garske to James Audibert. Who is Margaret Garske?

A. She's a clinical research coordinator for Upsher-Smith.

Q. And what is this letter about?

A. This is a letter which she's sending me copies of four protocols, of studies that were done with Niacor-SR, and it says it's being sent to me as requested by Mark Halvorsen, so I suspect in my discussions with Mark, I was asking him could he send me protocols of the studies.

Q. And once you received these protocols, what did you do with them?

A. I sent them on to Dr. Veltri, who was the vice president of clinical research for cardiovascular at Schering-Plough.

Q. And what was the purpose for doing that?

A. So that Dr. Veltri could at least familiarize himself with the overall study design, so -- because again, later on, he would then be reviewing the overall ISS and ISE. So, by him knowing now just what the study designs were, it would be easy for him to do that review at a later date.

Q. Okay, I'm putting now -- I'd like you to turn now to a document bearing SPX 243. It's a document dated August 21st, 1997, and it says it's from you to Rick Veltri. Again, who is Dr. Veltri?

A. Dr. Veltri is a cardiologist who's the vice president of clinical research for Schering-Plough for the cardiovascular area.

Q. And what is this document doing?

A. Just putting him -- I'm doing two things. One, I'm sending him the protocols that I had just received, and also, put him on notice that I will be looking to -- for him or somebody in his group to participate in reviewing all the clinical studies results when they are available as a part of putting together our international dossier.

Q. Now, it says, "I would like us to review the clinical documents but at this time, they are still compiling reports and it is unlikely that we will have

something to look at before the end of October."

Had you already begun to sense that there were going to be at least some modest delays?

A. It was hard to tell at that time. It looked like they may be slowing down a little bit, but again, the end of October was still the end -- was the target date for the ISS/ISE. So, potentially at that point in time we could still have those documents when we had anticipated getting them.

Q. I'd like you to turn now to a document bearing SPX 244. It's also dated August 21, 1997, and it says it's from Jim Audibert to Michael Perelman. Who is Mr. Perelman?

A. Dr. Perelman is a director in our worldwide regulatory affairs, so he would be working -- he's at Kenilworth. He would be working with Dr. Osselaere, who's based in Belgium, to put together the filings for Europe.

Q. And Kenilworth is in New Jersey, USA?

A. Yes, that's the headquarters.

Q. So -- and what's the purpose of this document?

A. Again, to put him on notice that we, again, will be putting together a team to review the Niacor-SR documents, and just, again, to let him know that we are going to be putting a group together to do that.

Q. And it says, "Could you or Lisa review these documents."

Do you know what documents you were sending him?

A. No, I don't know what was attached. I don't know if there was anything attached to it or not.

Q. And now I'd like you to turn to a document bearing Exhibit Number SPX 245. It bears the date August 21, 1997. It says it's from Jim Audibert to Dr. Bill Carlock. What is the purpose of this document?

A. Dr. Carlock works for our international technical operations group, which would be the group that would be responsible for making the product should we decide to make the Niacor-SR product. So, I was providing him some agreements -- again, I'm not sure what was there, but it says a specially proposed manufacturing agreement. So, I'm providing him some materials. I don't know and I don't recollect exactly what those materials were.

Q. But it may have been a draft manufacturing agreement?

A. Yeah, I suspect by the language there, it probably was a draft of the manufacturing agreement.

Q. Now I'm going to put in front of you a document -- or I'd like you to turn to a document

marked SPX 10. Do you have that?

A. Yes.

Q. This is a letter from James M. Audibert to Margaret Garske dated August 21, 1997, and what is this document about?

A. Mrs. Garske had sent me the four protocols, so I was sending a note, one, thanking her for sending me the protocols and also asking her for a list of the investigators who participated in two of the studies there, and the reason I was interested in that, I wanted to see who was doing -- who they had used for their studies and compare that to who were doing studies with us for ezetimibe to see if there was any overlap.

Q. Now I'd like you to turn to a document in your binder that bears number SPX 11. Do you have that?

A. Yes.

Q. This one's hard to read on the ELMO.

It starts -- this is another document dated August 21, 1997. It says it's from Jim Audibert to Ray Kapur, copy to T. Lauda. What is this document about?

A. This is a document that I provided to Mr. Kapur keeping him updated on the status of my activities with Niacor-SR, and in my document, I told him that I was trying to arrange a trip for Dr. Osselaere to go out

and visit Upsher-Smith, but we were having difficulty doing that because the data was not available as we originally thought it would be.

Q. Okay. Now I would like to -- you to turn to a document bearing SPX 648. Do you have that?

A. Yes.

Q. And this document is dated October 21st, 1997. It's from Ray Kapur to Ian Troup at Upsher-Smith Labs, and it shows a copy to James Audibert. What is this document about?

A. This is Mr. Kapur now asking Mr. Troup if the information that we were hoping to get by mid-October would be available and could we go ahead and -- could we then go ahead and set up a meeting to bring people from Kenilworth to go out and look at this information at Upsher-Smith.

Q. Do you know -- do you recall at this point in time, Mr. Audibert, whether this letter was sent at your request or for some other reason?

A. I don't remember the specifics behind this in terms of whether I had asked Ray to write it or not. I could have. I just don't have a clear recollection of what prompted this letter.

Q. Okay. In any event, was there a meeting that actually took place in October with Mr. Osselaere or

anyone else from Schering?

A. No, because the -- at that point, there was not sufficient information available that would warrant us taking a trip out there to look at what they had.

Q. Okay, now I'd like you to turn to a document bearing SPX 12. It is -- it bears the date November 7th, 1997. It's from Ray Kapur to Jim Audibert. And what is this document about?

A. This talks about -- it's a memo again from Ray to myself indicating that he had -- Ray -- had run into Mr. Troup from Upsher-Smith at a meeting the week before and that Mr. Troup agreed to send us the Niacor registration in segments that would now allow us to start at least looking at the information rather than getting the full ISS/ISE.

Q. Now, this is dated November the 7th. Did anything relevant to the Niacor-SR project happen at about that time?

A. About this time, as I mentioned before, Kos had announced their first quarterly results of Niaspan sales in the U.S., and as I mentioned before, those results were considerably below the expectations of I think just about everyone.

Q. And did you get the ISS/ISE or even get it in segments in November-December 1997?

A. No, no.
Q. More delays?
A. Yes. I mean, we waited for the information, and it actually never came.
Q. Now, I'd like you to turn to a document bearing SPX 13. Do you have that in front of you?
A. Yes.
Q. And it is dated April 15, 1998, and what is -- it's from RK or Ray, who is that?
A. It is Ray Kapur.
Q. Okay, and it says to Messrs. Audibert and Lauda. What is this document about?
A. This is a request from Mr. Kapur to -- Ray -- to Mr. Lauda and myself to sign a confidentiality agreement between us and Upsher-Smith which would then allow Upsher-Smith to send us information on Niacor.
Q. And then I'd like you to take a look at a document that is -- bears SPX 251, and you'll find that in binder two, I believe.
A. Oh. 251 you said?
Q. Yes.
A. Okay.
Q. Do you have that?
A. Yes.
Q. It's a letter from Desiree D. Malanga, it says

secretary to Mr. R. Kapur, to Vickie O'Neill, director of business development at Upsher-Smith. What's this?

A. This is now the executed confidentiality agreement that we had just previously talked about that -- I don't know who signed it, I don't know if Tom signed it -- I don't -- oh, Tom signed it. I don't have the legal authority to sign these, so I really wasn't involved in it, and so this is a note from Mr. Kapur's secretary sending this signed confidentiality agreement back to Upsher-Smith and then asking them to send the Niacor information directly to Mr. Lauda.

Q. And -- yeah, it says, "In addition, we request that complete information with regard to Niacor be sent directly to Mr. Thomas Lauda."

And I take it you were still trying to get the ISS/ISE data?

A. We were still waiting for the clinical reports and the ISS/ISE, that's correct.

Q. Now I'd like you to turn to a document that bears SPX 15, that's in binder one. Do you have that?

A. Yes.

Q. This is a memorandum from Jim Audibert to Tom Lauda. It's dated September 25th, 1998. It shows copy to R. Kapur. What is this document about?

A. This -- this memo summarizes a discussion that

Mr. Kapur and I had had with Upsher-Smith, Mr. Troup from Upsher-Smith, the day before that basically said that Upsher-Smith was not going forward with their NDA for a number of different reasons, and therefore, this raised some real issues about the potential commercial viability of Niacor-SR from our perspective or at least from my perspective.

Q. And was it at about this time that Schering made its decision not to proceed?

A. Yes.

Q. Now, on the bottom of this document, it -- you have written, "Uptake of Niaspan in the U.S. has been poor. Sales for the first 6 months of 1998 totaled $3.8 million and in August 1998, after being in the market one year, Niaspan's new Rx share for the month is only 1.1%. Furthermore, judging by the response of the investment community, the prognosis of Niaspan is poor. The current price of Kos' stock is 5 and 7/16, down from 44 last October."

How did you know the stock prices of Kos at that time?

A. Well, the fact that Kos was run by a number of people that, you know, I personally knew, Mike Jaharis, Mike Baldini, a number of different people, I would see how they were doing. I mean, just personal interest,

but also it was a good way of also looking at how other people are valuating the potential for Niaspan, because the analysts spend a lot of time -- you know, they would be looking at what they saw as the outlook for the product, and by the stock going from 44 to 5 and 7/16 would indicate that the analysts had some serious reservations as to how they thought the stock was -- how the product was eventually going to do.

Q. At the end of this memo, you state that the outlook is bleak, although you're still waiting for the clinical data.

A. Yes, we are still waiting for the information, so you couldn't make a final assessment at that point in time; however, when one looks at all the facts, the fact that Niaspan had been doing poorly, Upsher-Smith was not going to do any work on the NDA, which meant we would have to do all the work ourselves. We would be considerably later into the market than we originally anticipated. It probably didn't make sense going forth with this particular product.

MR. NIELDS: May I have a moment, Your Honor?

JUDGE CHAPPELL: Yes, you may.

MR. NIELDS: I have nothing further.

JUDGE CHAPPELL: Thank you. Is there going to be any direct exam by Upsher-Smith?

MR. CURRAN: No, Your Honor.

JUDGE CHAPPELL: Cross?

MR. EISENSTAT: Yes, Your Honor.

JUDGE CHAPPELL: You may proceed.

CROSS EXAMINATION

BY MR. EISENSTAT:

Q. Hello, Mr. Audibert.

A. Mr. Eisenstat.

Q. Going back to June of 1997 when you were first assigned to work on the Niacor-SR, do you recall when that was?

A. Which date exactly was it?

Q. Yes.

A. No, I don't remember which date.

Q. Could you look at CX 1042? It's in binder one. Do you have that in front of you?

A. Yes.

Q. If you look on the second page, the second page has a -- is a little clearer at the top, do you see the fax transmission line?

A. Yes.

Q. And that reads, "June 12th, '97, Thursday, 16:34"?

A. Yes.

Q. And you didn't start your work, your evaluation

specifically, of Upsher's Niacor-SR product until after you received this document. Is that right?

A. I'm sorry, what was the question again?

Q. You didn't start your work, your evaluation specifically of Upsher's Niacor-SR product until after you received this document. Is that right?

A. That's correct.

Q. Okay. So, is it fairly clear to you then that you didn't start your project until after June 12th?

A. Yes.

Q. And when did you finish your analysis, your evaluation of Upsher's Niacor-SR product?

A. Again, I don't remember the specific date.

Q. Well, again, let's look at the document, see if there's a date on that. Could you turn to SPX 2? Do you have that in front of you?

A. Yes.

Q. And is this the copy of the document by which Mr. Lauda transmitted your analysis to Mr. Kapur?

A. Yes.

Q. And is the document dated?

A. Yes.

Q. And what's the date on the document?

A. June 17th.

Q. Okay. Now, if you look at the top of the page,

again, there seems to be a fax transmission line that records the date and time of the transmission. Do you see that?

A. Yes.

Q. And that says, "June 17th, '97, Tuesday, 9:31." Is that right?

A. Yes.

Q. Okay. So, it appears then that you started your analysis on June 12th, and you had completed it before Mr. Lauda sent this fax off on June 17th. Is that right?

A. Yes.

Q. Okay. Now, June 12th, if we go back to CX 1042 -- okay, do you have that in front of you?

A. Yes.

Q. Now, the facsimile transmission line on that shows that that was a Thursday, the 12th of June. Do you see that?

A. Yes.

Q. Do you recall actually getting a fax transmission with this material yourself?

A. No, I don't remember specifically -- no.

Q. Do you remember if Mr. Lauda actually physically gave you the information?

A. I don't remember how it physically came into my

hands.

Q. Okay. Do you remember working on the project that Thursday?

A. That -- do I remember working on that project specifically on June 12th, 1997? No.

Q. You said that -- I believe you said that Mr. Lauda wanted these things done, he wanted them done quickly. Is that right?

A. Yes.

Q. Okay. Let's assume you started on that Thursday, count that as day one. Do you remember working on it the next day, on Friday, the 13th?

A. No.

Q. Okay. Do you think this would have taken more than a day to do?

A. Maybe a little bit more but not -- not much more.

Q. Okay. Well, let's -- counting Thursday, let's count Friday, that's day two. Do you remember if you came in to work on the weekend?

A. No, I don't remember, but it was frequent for me to take work home at night and the weekends.

Q. So, that was a -- something you would --

A. Oh, very common, yes.

Q. Okay. Would you work typically -- when you --

you're no longer in global marketing. That's correct?

A. That's correct.

Q. And Mr. Lauda's no longer your superior?

A. That's correct.

Q. Okay. When you were back in global marketing and Mr. Lauda was your superior, if you took work home on the weekend, would you typically work both days, Saturday and Sunday?

A. More likely one or the other.

Q. Okay. Count one of those days, Thursday, Friday, Saturday, that's three days. Do you remember working on the project on Monday?

A. No, again, I cannot remember specifically which days during that time period I worked on the product -- on the project.

Q. Okay. When you did a project such as this for Mr. Lauda, would you show him the finished product before you put it in final and sent it out?

A. What I would usually do, I would finish what I would see as my final document, and I would sit down with him and just review it so he clearly understood what I was writing, because there may be something that I wrote that was clear to me but wasn't clear to him, and if there were some minor modifications, I would make those changes and then give him the final

document, but what I would usually give him is the -- my final version of the document, pending any small changes he wanted to make.

Q. Do you recall if you did that in this case?

A. I just don't have any recollection, whether I specifically did that here.

Q. If you did do that, that would have been done before he sent it out to Mr. Kapur?

A. Yes.

Q. Okay. And he sent it out to Mr. Kapur on Tuesday, so -- at 9:31, so at most that's Monday and Tuesday, so you spent, what, at most five days working on this?

A. At most, right.

Q. And your instructions came from your superior, Mr. Lauda. Is that correct?

A. Yes.

Q. And they were to do a commercial assessment of Niacor-SR. Isn't that correct?

A. That's correct.

Q. And more specifically, you were told to generate a sales forecast for Niacor-SR based on the information that you were provided, correct?

A. Yes.

Q. And then later on you were asked to do the

profit and loss statement for your sales projections. Is that right?

A. Yes.

Q. But you were asked to do that before the end of the 17th, weren't you?

A. I -- I don't remember what the date -- when that was actually requested and when I did it.

Q. Okay. Well, let's go back and see when you did that. Now, SPX 2 was Mr. Lauda's transmittal of your commercial assessment to Mr. Kapur. SPX 6, is that your profit and loss?

A. Yes.

Q. Okay. And that's also dated June 17th?

A. Yes.

Q. And that also bears a fax transmission line?

A. Yes.

Q. And that shows you sent this out on June 17th, Tuesday, at 10:22?

A. Yes.

Q. Okay. So, it was sometime before that that you were asked to do the profit and loss.

A. Yes.

Q. But aside from those two projects, you were not asked to do anything else with respect to Niacor-SR before June 17th.

A. That is correct.

Q. While you were spending at most five days working on your evaluation of Niacor-SR, did you go to Upsher-Smith's offices to meet with them?

A. No.

Q. While you were working on your evaluation for Niacor-SR, these five days, did you meet with anybody anywhere from Upsher-Smith about Niacor-SR?

A. No.

Q. While you were doing your evaluation, this commercial assessment that you did, for Niacor-SR, did you have any conversations with anybody from Upsher-Smith?

A. No.

Q. But you were given some information before you started your work on the project, and those are documents that you reviewed this morning?

A. Yes.

Q. Let's turn again to CX 1042, and you testified this morning that this was one of the documents you were given to work on the -- your evaluation of Niacor-SR. Is that right?

A. Yes.

Q. And this information contained -- or this document contains information about two Upsher-Smith

trials about Niacor-SR. Is that right?

A. Yes.

Q. Okay. And one of them's protocol 920115? Well, let me direct your attention to page SP 1600079 and see if that helps us get this.

A. 79. Okay, so, I'm sorry, what was the question again?

Q. Okay. One of the -- one of the protocols that you got information on was 920115. Is that right?

A. Yes.

Q. And another was 900221. Is that correct?

A. That's correct.

Q. And you also got information on two follow-on studies, 920944 and 920837. Is that right?

A. I don't know if those are the correct numbers.

Q. Well, maybe I have the wrong number.

A. I don't know. I just don't --

Q. Do you have that page, SP 1600079, in front of you?

A. 0079.

Q. And if you look at -- do you have that page in front of you?

A. Yes.

Q. And if you look at the top, it says, "Niacor-SR (Polygel Controlled-Release Niacin) Clinical

Development Program."

Do you see that at the top of the page?

A. Yes.

Q. And beyond that is a listing of four studies. Do you see that?

A. Yes.

Q. And the first is 900221, and that's one of the studies that Upsher-Smith did. Is that right?

A. Yes.

Q. And the next listed one is 920837, and that's a follow-on study. Is that right?

A. Yes.

Q. And that's the follow-on study to the 900221 study?

A. But I'm just not sure what your question is, just to be sure I'm answering the right question.

Q. Is that the follow-on study to that 900221 study?

A. Yes.

Q. Okay. The other -- and these are sometimes called pivotal trials?

A. Pivotal -- pivotal trials, yes.

MR. NIELDS: Wait, objection, vague. It's not clear what he's referring to --

MR. EISENSTAT: Let me clarify that, you're

right.

BY MR. EISENSTAT:

Q. 900221 is one of what would be called pivotal trials. Is that right?

A. That's correct.

Q. And 920115 is another study, what would be called a pivotal trial. Is that right?

A. That's correct.

Q. And 920944, that's a follow-on study to 920115. Is that right?

A. That's correct.

Q. Okay. And these are the only four trials that you got any information on from Upsher-Smith before you did your five-day study of the Niacor-SR.

A. No, I was also provided some synopsises of -- two synopsises of two protocols that they were planning to do.

Q. Okay. My question is, these were the only studies that you got information that talked about the study results.

A. Oh, I'm sorry. Yes, the 221 and the 115, that's correct.

Q. Okay. Let's look at one of those protocols. Could you turn to SPX 4? Do you have that in front of you?

A. Yes.

Q. And this is the draft protocol synopsis that you received at the same time when you were going to do your five-day study of Niacor-SR?

A. Yes.

Q. And at the top it has the same fax line, right, 6/12/97, Thursday, it was received at the same time?

A. Yes.

Q. Now, this is a protocol synopsis for a clinical study that hadn't been done yet. Isn't that correct?

A. That is correct.

Q. And did the synopsis tell you when the study was going to be done?

A. I don't remember if it did or not.

Q. Is there a place that would tell us that without having to go through the whole document?

A. Usually not.

Q. Usually there's no set place or usually they don't tell you when they are going to do it?

A. In my experience, usually in a synopsis, it does not have the estimated start date of the study.

Q. So, if I want -- if we went through this and couldn't find the start date of the study, that wouldn't surprise you.

A. No.

Q. When you did your analysis of Niacor-SR, the five-day study of Niacor-SR that you did, did you make any assumption as to when this protocol would be done or this clinical study would be done?

A. I assumed that the study was going to be started relatively soon, but I was not assuming that this study was going to be done in time to have as a part of its initial filing.

Q. And what was it based on that you assumed that it would be done relatively soon?

A. I don't know what was the -- the fact that they had -- based on my experience, you usually don't do protocol synopsis like this unless the study was going to be done fairly soon.

Q. Did you pick up the phone and call anybody from Upsher-Smith and ask them, when's this study going to be done?

A. No.

Q. Did you pick up the phone and call anybody at Upsher-Smith and ask them even if it was scheduled yet to be done?

A. No.

Q. Let's turn to SPX 71. This is another draft protocol synopsis.

A. Yes.

Q. And you received this with the same package of other information you got before you did your five-day study on Niacor-SR?

A. Again, I don't remember exactly how it -- what format it came, whether the two protocols were together with the other package. I don't remember getting each individual piece, how it came.

Q. Okay. This, though, has the same fax transmission line across the top, does it not, June --

A. Yes.

Q. -- June 12th, '97, Thursday?

A. Yes.

Q. Had the study that's described in this draft protocol synopsis, had that been done when you received this package of information from Upsher-Smith?

A. No, I believe this was a planned study, not -- it had not -- I believe it had not been done.

Q. And you didn't know when this study was going to be done either, did you?

A. No.

Q. And you didn't call anybody from Upsher-Smith and ask them when this was going to be done, did you?

A. No.

Q. And you didn't call anybody from Upsher-Smith and ask them whether they were going to actually go

forward on this study, did you?

A. No.

Q. The two protocol synopsis, the one that's SPX 4 and the other that's SPX 71, did you give them -- at the time you were doing your five-day study on Niacor-SR, did you give these to --

MR. NIELDS: I object to the form of the question. This witness has not said he spent five days on this study. He hasn't said how many days. It's only been established that there was five days between when he got the information and when he did the report. It could have been a four-day study, three-day, two-day, one-day.

MR. EISENSTAT: I'm just giving him the benefit of the doubt, Your Honor, and assuming he spent that much time on the study. They spent $60 million on the drug based on this study, and I'm just giving him the benefit of the doubt that he spent that much time on it.

JUDGE CHAPPELL: So, your response is that you're asking him if he spent five days, not asserting it?

MR. EISENSTAT: Yeah, I'm -- I think I've established that he spent no more than five days, so I'm just -- I'm using that to characterize the study

just so we know which study we're talking about.

JUDGE CHAPPELL: I am going to sustain the objection. Restate it in another form, Mr. Eisenstat.

BY MR. EISENSTAT:

Q. Okay, when you did your work -- your study on -- or your commercial assessment of Niacor-SR between June 12th and June 17th, did you show these -- either of these protocol synopsis to anybody at SPRI?

A. No.

Q. Now, just turning once more to SPX 71, the two-page protocol synopsis, do you see any date on this document that tells you when they were going to do the study?

A. No.

Q. In the period from June 12th through June 17th when you did your commercial assessment on Niacor-SR, nobody asked you to do any due diligence regarding Niacor-SR beyond the papers that you were given, did they?

A. That's correct, I was not asked to do any of the due diligence.

Q. And aside from the sales forecast and profit and loss statement that you produced, you weren't asked to do anything else on the Niacor-SR product between June 12th and June 17th.

A. That is correct.

Q. And aside from the sales forecast and profit and loss statement, you didn't do anything else regarding the Niacor-SR product before the license agreement was signed between Upsher-Smith and Schering, did you?

A. Yes, in terms of working on it, yes, I did nothing else.

Q. Now, the NDA for the Kos Niaspan product had been filed by Kos with the FDA before you began your assessment of Niacor-SR. Is that right?

A. That's correct.

Q. But the NDA for Niacor-SR had not been filed yet by Upsher-Smith before you began working on the Upsher-Smith product. Is that right?

A. That's correct.

Q. When you were asked to work on Niacor-SR, you did not contact Karin Gast and ask her if she had learned anything about the sustained release niacin products after you stopped working with it, did you?

A. That is correct.

Q. And during the period June 12th through June 17th when you were doing your commercial assessment of Niacor-SR, you did not talk to Karin Gast about Niacor-SR at all.

A. That is correct.

Q. During the period June 12th to June 17th when you were doing your commercial assessment of Niacor-SR, you did not contact Ray Russo and ask him if he learned anything about sustained release niacin after you dropped out of the Niaspan project.

A. Not that I recollect, no.

Q. And during the period June 12th to June 17th when you were working on your commercial assessment of Niacor-SR, you didn't contact anyone from the Schering-Plough Research Institute about Niacor-SR.

A. That is correct.

Q. Did the information that you were provided to do your commercial assessment of Niacor-SR, did that tell you whether there were any problems that the FDA identified to Upsher-Smith in the communications between the FDA and Upsher-Smith?

A. No, it did not.

Q. That's something you would want to know, isn't it, before you did your commercial assessment of Upsher-Smith's Niacor-SR, whether the FDA had identified any problems with the product?

A. Not necessarily.

Q. It would not be of concern to you in doing a commercial assessment of a product whether or not the

FDA had identified problems with the product?

MR. CURRAN: Objection, Your Honor, vague. The question refers to a commercial assessment. I'm not clear whether he's talking about a commercial assessment for the European market or the U.S. market.

JUDGE CHAPPELL: Did you understand the question?

THE WITNESS: No, I would like to have it repeated at least.

JUDGE CHAPPELL: I sustain the objection.

BY MR. EISENSTAT:

Q. You only did one commercial assessment of Niacor-SR. Isn't that right?

A. That's correct.

Q. Okay. And that was the one you did between June 12th and June 17th. Is that right?

A. That is correct.

Q. When you were doing your commercial assessment of Niacor-SR between June 12th and June 17th, would you want to know whether the FDA had told Upsher-Smith that there were -- that they had found problems with the product?

A. I would certainly want to know if there were potential issues that could affect the information that was in the packet.

Q. Would you want to know if there was information that could lead to a delay in getting the NDA filed by Upsher-Smith?

A. Well, my assumptions were based on the information contained in the packet. So, I guess in answer to your question, if there were other information that would conflict with the information in the packet, then yes, that would be important to know.

Q. Now, the information that you were provided did not tell you whether there were any additional studies besides the studies identified in CX 1042 that the FDA was requiring from Upsher-Smith, did it?

A. That is correct.

Q. Is that something you would want to know before you did your commercial assessment of Upsher's Niacor-SR between June 12th and June 17th?

A. Well, again, as I previously stated, if there was something that would change the information that's in the packet that I was provided, yes, that was something I would want to know.

Q. Would you want to know that the FDA was requiring additional studies beyond the studies identified in 1042, CX 1042, before you did your commercial assessment of Niacor-SR?

A. I guess it would be dependent upon what -- the

reason for those requests.

MR. EISENSTAT: One moment, Your Honor.

(Brief pause.)

BY MR. EISENSTAT:

Q. Mr. Audibert, you know what a pharmacokinetic study is, don't you?

A. Yes.

Q. And a pharmacokinetic study profiles the rate and extent of absorption of the product into the body?

A. That is correct.

Q. And a pharmacokinetic study is required in order to file an NDA for a product?

A. I do not know whether that is -- that's true or not.

Q. Do you know whether the FDA was requiring of Upsher-Smith to file a pharmacokinetic study in order to file their NDA?

A. I do not know if they did or didn't.

Q. Is that something you would want to know before you did your commercial assessment of Niacor-SR between June 12th and June 17th?

A. Not necessarily.

MR. EISENSTAT: May I approach the witness, Your Honor?

JUDGE CHAPPELL: Yes, you may.

BY MR. EISENSTAT:

Q. Mr. Audibert, I'm going to hand you what's been marked as CX 1379, and this is a document from the files of Upsher-Smith that has already been admitted into evidence in this proceeding. I'll give you just a moment to look over that document.

A. (Document review.) Okay.

Q. Have you had a chance to look it over?

A. Yes.

Q. Now, this is a facsimile from the Center for Drug Evaluation and Research at the FDA to Upsher-Smith. Do you see that?

A. Yes.

Q. And it bears the date January 13th, 1997. Do you see that?

A. Yes.

Q. Now, it's not unusual for the FDA to communicate by fax to companies that have filed or working to file an NDA, is it?

A. I am -- I don't know. I mean, I'm not in the regulatory area, haven't been in the regulatory area for -- since 1977, so I don't know how the FDA communicates with companies these days.

Q. When you have looked at products that Upsher-Smith -- excuse me, when you have looked at

products that Schering is going to in-license, candidates for possible in-licensing of a drug, have you reviewed FDA files of the company -- from the companies you're in-licensing the drug from?

A. Have I reviewed? Repeat the question, please.

Q. Sure. When Schering's considering in-licensing drugs in the past, you've worked on projects like that. Is that right?

A. Yes.

Q. When you worked on projects where Schering was considering in-licensing a drug, did you ever review files of documents, communications between the company you were proposing to license the drug from and the FDA?

A. Me personally, it was very unusual for me to look at those type of documents.

Q. Did you ever do it?

A. I might have. I don't have any distinct recollection of doing it.

Q. So, looking at this document, you don't know if it's a red flag that, in fact, the Center for Drug Evaluation and Research at the FDA sent a fax to Upsher-Smith or if this was just the normal course of business?

A. That is correct.

Q. Could you turn to the second page of the document, the -- it bears the number 107530, if you could see that at the bottom, also it says page 1 at the top, which is probably easier to see.

Do you see the very first sentence of the first paragraph there? It says, "We have good reason to believe that your inability to detect niacin and niacin metabolites in plasma is due to inadequate study design of Protocol 901455."

Do you see that sentence?

A. Yes.

Q. Do you know what protocol 901455 is?

A. No.

Q. Do you know what metabolites are?

A. Yes.

Q. And what are metabolites?

A. Metabolites are when a drug is ingested into the body, and then the body breaks it down or metabolizes it, those pieces are each called a metabolite.

Q. Okay. And it's important for Upsher-Smith to detect niacin and niacin metabolites in order to show the pharmacokinetic properties of Niacor-SR. Is that right?

A. Again, I'm not familiar what the FDA's

requirements are from a pharmacokinetic point of view.

Q. You just don't know?

A. I don't know what the FDA in this particular case is specifically looking at.

Q. Let's go down that page a little bit to the paragraph numbered 3. Do you see that paragraph? And it reads, "The following studies will need to be performed to support the Human Pharmacokinetics and Bioavailability section of a future NDA submission for this product."

Do you see that?

A. Yes.

Q. And this -- just to make the record clear, this is all about Niacor-SR, right? At the top of the page, it --

A. Yes.

Q. Okay. And the first study listed is under A, "Single-dose randomized crossover bioavailability/dosage form equivalence study comparing each dosage strength you intend to market with the currently-marketed immediate-release form of niacin. The dose given should be sufficient to detect above baseline levels (1500-2000 mg)."

Do you see that study?

A. Yes.

Q. And the second study is B, "Single-dose randomized crossover food-effect study comparing Nicolar under the following conditions: 1, fasting, 2, immediately after a high-fat breakfast, 3, immediately after a low-fat breakfast. The purpose of treatment 2 is to determine whether the dosage form will fail (and 'dump' niacin) after this type of meal. Treatment 3 is the type of meal that a hypercholesterolemic patient might be expected to consume."

Do you see that study?

A. Yes.

Q. Do you have any experience in doing these kinds of studies with niacin?

A. With niacin? No.

Q. Yes, sir.

And the third study is, "Multiple-dose, randomized, crossover study using the dosing regimen(s) used in the Phase III trials."

Do you see that?

A. Yes.

Q. And then under D it says, "As discussed in the 7/17/95 meeting, if the equipment, process, site, and formulation changes proposed by USL are carried out, a bioequivalence study between the formulations used in the clinical trials and the to-be-marketed formulations

will be needed."

Do you see that?

A. Yes.

Q. That refers to a 7/17/95 meeting. Do you see that reference?

A. Yes.

Q. It's not unusual for companies that are working on drugs with the FDA to file for an NDA, not unusual for them to have meetings with FDA, is it?

A. No.

Q. Now, when you did your study between June 12th and June 17th, your commercial assessment of Niacor-SR, you had not seen this document, had you?

A. That's correct.

Q. And if Upsher couldn't satisfy the FDA on the studies necessary to show the pharmacokinetic properties of Niacor-SR, Upsher-Smith couldn't get its drug approved. Isn't that right?

A. If -- if the FDA held to their position in this document.

Q. And if Upsher couldn't satisfy the FDA on the studies necessary to show the pharmacokinetic properties of the Niacor-SR before the end of 1997, it could jeopardize the schedule for getting approval of Niacor-SR. Isn't that right?

A. Again, assuming the FDA stuck to their position in this memo, yes.

Q. The next document I'm going to show you has been marked CX 1382. This is also a document from the files of Upsher-Smith and also a document that is in evidence in this case.

Without asking you to read the whole document, can you tell if you've ever seen this document before?

A. I don't believe I've ever seen this before.

Q. So, when you did your study of -- your commercial assessment of Niacor-SR between June 12th and June 17th, 1997, you had not seen this document when you did that?

A. That's correct.

Q. Let's turn in the document to the page, and there's a number on the bottom of the page, 107433, and at the top of the page it says, "Upsher-Smith Laboratories, Inc.," and then there's a line that's hard to read, and then there's -- a line that says, "With FDA regarding Niacor-SR, IND number 37,984."

Do you see that?

A. Yes.

Q. And the first paragraph on this page reads, "On February 5th, 1997, Upsher-Smith Laboratories, Inc. representatives met with FDA representatives from the

Division of Pharmaceutical Evaluation II and the Division of Metabolism and Endocrine Drug Products to discuss pharmacokinetic issues regarding Niacor-SR."

Do you see that?

A. Yes.

Q. Now, when a company meets with the FDA, when they're working to get a drug approved and they meet with the FDA about their drug, is it common for them to write up minutes of that meeting and send it to the FDA?

A. I'm not really sure what is commonly done in terms of interaction between pharmaceutical companies and the FDA.

Q. Let's go back to the very first page of the document, the page dated February 24th, 1997. It appears to be a letter from Mark B. Halvorsen to Solomon Sobel. Do you see that?

A. Yes.

Q. Do you know who Mark Halvorsen is?

A. He's -- he works at Upsher-Smith. I'm not exactly sure what his title was.

Q. He was the contact name you were given, wasn't he?

A. Yes, I had talked to him, yes.

Q. Do you know who Solomon Sobel is?

A. No.

Q. The second page -- the second paragraph of that page says -- of that first page says, "Enclosed is a copy of the Upsher-Smith February 5th, 1997 meeting minutes for your review (see Attachment 1)."

Do you see that?

A. Yes.

Q. And you don't know, I believe you said, that you don't know whether that is a common occurrence for people to send meeting minutes to the FDA?

A. That is correct, I don't know what is commonly done.

Q. Have you ever heard of that being done?

A. Yes.

Q. When you did your commercial assessment of Niacor-SR between June 12th and June 17th, you didn't look at any files from the FDA from Upsher-Smith, did you?

A. No, I did not.

Q. Let's go back to the first page of the meeting minutes. It's the page bearing the number 107433 at the bottom, where it says at the top, "Upsher-Smith Laboratories, Inc. " Do you have that page in front of you?

A. Yes.

Q. And do you see there's a list of representatives in attendance at this meeting do you see this?

A. There's two lists.

Q. Right, there's one list for the FDA and one list for Upsher-Smith, right?

A. Yes.

Q. Do you see the name Mike Fossler, Ph.D., Pharmacokinetics Reviewer under the FDA list?

A. Yes.

Q. And do you see the name John Hunt, Deputy Director of Pharmaceutical Evaluation II also under the FDA list?

A. Yes.

Q. Now, let's turn to the next page of the document, and the second paragraph on this page, do you see that paragraph that reads:

"Dr. Fossler explained that the issue is qualifying the product for a sustained-release or extended-release claim. The efficacy and bioavailability conditions are probably met and the application is probably fileable with existing data without an extended release claim. In order to obtain an extended-release claim, metabolite levels need to be detectable showing the differences between an

immediate-release and the extended-release dosage form. Mr. Hunt supported Dr. Fossler's explanation, indicating that Upsher-Smith does not have adequate data to meet the regulatory requirements for an extended-release product."

Now, was it important for Upsher-Smith to get a -- to be able to show this as an extended release product?

A. I guess I'd have to think about that a bit. I mean, clearly at the end of the day, the medical community judges a product based on the clinical results, and in some cases, this nomenclature could become sort of semantics. I would offer it would probably be better to have a term like extended release, sustained release, but again, based on my experience, physicians at the end of the day judge a product based on the facts, the clinical facts of the product, you know, not whether it's met some regulatory requirement or definition.

Q. There were immediate release prescription niacin products on the market in 1997, were there not?

A. I believe over the -- over-the-counter --

Q. Do you know if there were prescription ones?

A. Niacin products?

Q. Niacin products.

A. I'm not aware of any niacin -- what year again now?

Q. 1997.

A. Ah, I'm not aware of -- I don't know if there were any on the market for prescription. I believe there were none for hypercholesterolemia.

Q. You don't recall one way or another whether there were immediate release niacin products available with a prescription in 1997?

A. As a prescription?

Q. As a prescription.

A. I don't believe -- I don't know for a fact, but I don't believe there were any.

Q. And there were sustained release niacin products on the market over the counter, were there not?

A. I believe that's what their regulatory status was.

Q. And the way Upsher-Smith was going to differentiate its product from immediate release niacin products was the fact that it was a sustained release that had lower flushing. Isn't that right?

A. The -- they would -- yes, they would differentiate the product using the clinical data that show it has less flushing, exactly.

Q. Would it have been important to Schering to be able to make a sustained release claim on the product in Europe?

A. It would certainly be desirable, but again, based on my experience, at the end of the day, the clinicians, the health authorities, they make the judgment and decisions on a product based on the clinical results, not the nomenclature around the product.

Q. Let's turn to the next page of the document, which bears the number 107435, it's a continuation of the Niacor-SR February 5th, 1997 meeting minutes, and let's look at the first full paragraph on this page.

"Dr. Fossler summarized that a crossover study between immediate-release and sustained-release products, evaluating for all the urinary metabolites, would be acceptable. Mr. Hunt commented that a lack of dose dumping would need to be demonstrated, as well. Considerable discussion followed regarding whether the already performed single dose study, although inadequate in design, may adequately demonstrate a lack of dose dumping under fed and fasted conditions. It was noted that the product will be labeled to take with meals."

Do you see that?

A. Yes.

Q. It was significant that the product was going to be labeled to take at meals, wasn't it?

A. No.

Q. Had you known when you did your study between June 12th and June 17th that Niacor-SR was to be labeled to take at meals?

A. No.

Q. And you got that wrong in your commercial assessment, didn't you?

A. Got it wrong in terms of -- what way did I get it wrong?

Q. That it was to be labeled to take at meals.

A. I didn't refer to it in my assessment, so I'm not sure how it can be wrong.

Q. Let's go back to your commercial assessment, which is SPX 2. Do you have that in front of you?

A. Yes.

Q. And let's turn to the page bearing the number SP 1600044. Do you have that in front of you? Do you have that page in front of you?

A. Yes.

Q. Now, just before I ask you any questions about it, you wrote this document, didn't you?

A. That's correct.

Q. And nobody else wrote any part of it. Is that right?

A. I took some of it -- I believe I took some of the charts in the beginning on some of the information from some of the Upsher-Smith charts in terms of the overall effect of various cholesterol-lowering agents.

Q. That would be the charts on SP 1600042?

A. That's correct.

Q. Okay, but you wrote the page SP 1600044. Is that right?

A. That's correct.

Q. And you describe Niacor as, "Niacor-SR is a patented, sustained-release niacin product designed to be administered at bedtime."

Did you write that?

A. That's correct.

Q. And in fact, it was going to be labeled to be taken at meals. Isn't that correct?

A. Based on what you've just told me, at that given point in time, at launch, it would appear that would be the case, but again, just so it's clear, when I write up my assumption here, I'm also looking over a -- the product, not just at launch, but what I see the product, the profile in the marketplace over some period of time.

Q. But certainly at the time you wrote the document, Niacor-SR was not a patented sustained release niacin product designed to be administered at bedtime, was it?

MR. CURRAN: Objection, foundation, Your Honor. Again, it's not clear whether he's talking about U.S. market or European market.

JUDGE CHAPPELL: I'll allow it if the witness can answer. Overruled.

THE WITNESS: At the time I wrote this, this statement is incorrect in the sense that the initial registration program was with twice-a-day dosing.

BY MR. EISENSTAT:

Q. Niaspan, when you looked at Niaspan, that was a once-a-day, at-night product, was it not?

A. That's correct.

Q. Let's turn to the next page on CX 1382.

A. That's which --

Q. Okay. The page bearing the number at the bottom 107436, also says page 4 on it. Do you have that page in front of you?

A. That's correct, yes. 46 you said, 436?

Q. 436. Do you see the last paragraph on that page? It says, "Dr. Robbins asked if the NDA would be fileable with the existing data and subsequently

amending the application with the results of the new study. There was considerable discussion regarding this proposal. Dr. Orloff concluded that under user fee regulations, the NDA should be approvable at the time of filing. Due to the known pharmacokinetic issues outstanding for Niacor-SR, the FDA should not file the NDA without the requested pharmacokinetic study results".

Do you see that?

A. Yes.

Q. Had you known this at the time you did your commercial assessment of Niacor-SR between June 12th and June 17th, 1997, you would have been in a position to decide whether to ask for more information from Upsher-Smith about the pharmacokinetic studies. Isn't that correct?

A. I would ask for information from Upsher-Smith or more likely I would probably consult one of our pharmacokineticists in SPRI and ask them what's the feasibility of doing these studies and have them in time for the NDA filing at the end of this year -- at the end of that year.

MR. EISENSTAT: Will you please reread the question?

(The record was read as follows:)

"QUESTION: Had you known this at the time you did your commercial assessment of Niacor-SR between June 12th and June 17th, 1997, you would have been in a position to decide whether to ask for more information from Upsher-Smith about the pharmacokinetic studies. Isn't that correct?"

BY MR. EISENSTAT:

Q. Can you answer that question?

A. And the answer is no.

Q. You would not have been in a position to ask for more information from Upsher-Smith?

A. No, because as I just said, the question in my mind, in terms of doing my commercial assessment, the real question would be does this request from the FDA change the deadlines that I used to make my commercial assessment, and that's the reason I would ask somebody in our pharmacokinetics area, is it possible to do these requested studies and still have them in time to file it within an NDA at the end of the year.

Q. Had you known about this document and what we just read about not -- about the FDA should not file the NDA without the requested pharmacokinetic study results, had you known that at the time that you did your commercial assessment of Niacor-SR between June 12th and June 17th, would you have been in a position

to ask Upsher-Smith when they were going to do the pharmacokinetic study?

MR. NIELDS: I object. I think there is a confusion in that question, I suspect, if Mr. Eisenstat reads it back, he's going to want to change it. I think he used the word "FDA " and he meant to use Upsher, but in any event, it's not intelligible to me.

JUDGE CHAPPELL: Did you understand it?

THE WITNESS: I'd prefer to have it read back.

MR. EISENSTAT: Can you read back the question, please?

(The record was read as follows:)

"QUESTION: Had you known about this document and what we just read about not -- about the FDA should not file the NDA without the requested pharmacokinetic study results, had you known that at the time that you did your commercial assessment of Niacor-SR between June 12th and June 17th, would you have been in a position to ask Upsher-Smith when they were going to do the pharmacokinetic study?"

THE WITNESS: I'm not sure what I would have asked Upsher-Smith myself, but I would have probably communicated to Mr. Lauda that just given the facts here, just to verify that these requests from the FDA were not going to change the filing deadlines -- time

lines that were in the document that I was provided.

JUDGE CHAPPELL: Since he answered it, I'll overrule the vagueness objection.

BY MR. EISENSTAT:

Q. And when you say you would have talked to Mr. Lauda, that would have been for him to confirm with Upsher-Smith?

A. Or -- again, I don't know what he would do with it, but I would want to make sure that he was aware that this -- I made my commercial assessment based on the data provided in the document that were provided -- the documents provided to me, if -- somebody should verify whether or not these requests from the FDA are going to change any of the information in that document.

Q. Let's turn to the next page of the document --

JUDGE CHAPPELL: Mr. Eisenstat, let me know when you're at a good breaking point.

MR. EISENSTAT: At your convenience. I'm always glad to take a break, Your Honor. We can do it now or --

JUDGE CHAPPELL: Why don't we take our lunch break. Let's take an hour. We will recess until 2:05.

(Whereupon, at 1:05 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(2:05 p.m.)

JUDGE CHAPPELL: You may proceed, Mr. Eisenstat.

BY MR. EISENSTAT:

Q. Mr. Audibert, we were talking about CX 1382. Do you still have that in front of you?

A. Yes.

Q. Could you turn to the page with the number on the bottom 107437? It's page 5 of the Niacor-SR February 5th, 1997 meeting minutes. Do you have that page in front of you?

A. Yes.

Q. And I'd like just to go over the summary at the top there where it says, "In summary, Upsher-Smith and the FDA agreed to the following conclusions:

"A 3-way crossover study will be performed with one 1000 mg immediate-release niacin fasted arm, and two 1000 mg sustained-release arms -- one fed and one fasted. There will be approximately 10 to 15 subjects per arm, with urine collection at predose 0-1, 2-4 -- 0-1, 1-2, 2-4, 4-6, 6-8, 8-12, and 12-24 hours post dose. Urinary excretion of niacin and its metabolites will be analyzed. Standardized meals will be administered throughout the study. No aspirin will be

used due to its affects (sic) on the metabolism of niacin. Upsher-Smith dissolution data to be provided will be evaluated to determine if a 250 mg arm, either fed or fasted, is necessary."

Do you see that part?

A. Yes.

Q. Do you know whether Upsher-Smith was ever required to add a fourth arm, this 250-milligram arm, to their pharmacokinetic study?

A. No, I do not.

Q. Let me show you a document that has been marked as CX 1383, and this is another document from the files of Upsher-Smith that has already been admitted into evidence in this proceeding, and this is another fax from the Center for Drug Evaluation and Research of the FDA to Upsher-Smith. This is dated March 26th, 1997.

You've never seen this document before, have you?

A. No, I have not.

Q. Let's turn to the second page of the document. Do you see the top paragraph there of the document, "Upon review of the comparative dissolution data, it appears that the 250 and 500 mg differ sufficiently such that a waiver of the requirement for pharmacokinetic data for the 250 mg tablet can not be

granted. Therefore, the proposed study design should be amended to include a fourth treatment arm administering 4 X 250 mg tablets under fed conditions."

Do you see that part?

A. Yes.

Q. At the time after the license was signed and you were working with people from Upsher-Smith, were you working solely with Mark Halvorsen?

A. Until I believe the -- well, what do you mean by working with him? I guess that's --

Q. Communicating with.

A. Well, I had communicated with Mr. Halvorsen in 1997, and I think as we discussed this morning, I had had some communications with the CRA, I don't remember her name, the clinical research associate who sent me the protocols, and I sent her a note thanking her and asking for a list of investigators, and then as the record showed this morning, I did have a conference call with Ian Troup, I believe, if I'm not mistaken.

Q. That is Garske, Ms. Garske?

A. Yes, Garske was the person.

Q. When you talked to the three of them, did they ever bring up the subject of the pharmacokinetic studies that they were required to do for their filing with the FDA?

A. No.

Q. Let's go to the second full paragraph here on this page, the page bearing the number 107457, again this fax from the FDA to Upsher-Smith.

"We continue to believe that the recommendations as faxed to Upsher-Smith on 1/13/97 represent the ideal manner in which to study the controlled-release characteristics of Niacor-SR. However, as discussed in the 2/5/97 meeting between your firm and the Agency, if Upsher-Smith feels that a single -- feels that single doses of niacin above 1000 mg represent a significant safety concern when given to normal volunteers, then the design as outlined in your submission dated 2/24/97 will be sufficient for filing, provided that a 250 mg treatment arm is added to the study. It is emphasized that approval of the Niacor-SR as a controlled-release product is dependent on the results of the submitted study, and not merely on its completion."

Do you see that?

A. Yes.

Q. Do you know if Upsher-Smith ever did their pharmacokinetic study?

A. I do not know.

Q. And you don't know what results they would have

gotten had they done the study.

A. No.

Q. Let me show you what's been marked as CX 1111, another document from the files of Upsher-Smith and a document that's been admitted into evidence.

JUDGE CHAPPELL: Yes, you may approach the witness.

MR. EISENSTAT: I'm sorry, Your Honor.

BY MR. EISENSTAT:

Q. Have you ever seen this document before, Mr. Audibert?

A. Yes, I believe I have.

Q. Do you recall if you saw it around the date on the document, October 6th, 1998?

A. I might have. I just don't remember if I saw it at that time.

Q. The first paragraph says, "Per your request to Ian Troup last week, I am writing to confirm that Upsher-Smith Laboratories, Inc. has suspended all research on Niacor-SR. There were multiple reasons for this decision. First and foremost, an additional multiple-dose pharmacokinetic study was required prior to submitting an NDA. In light of Niaspan's FDA approval, Upsher-Smith's NDA would have been two to three years behind the launch of Niaspan."

Did anybody from Upsher-Smith, while you were talking to them, ever tell you about the requirement of an additional multiple-dose pharmacokinetic study?

A. No.

Q. Did anybody at Upsher-Smith ever ask you for any assistance in doing pharmacokinetic studies on Niacor-SR?

A. No.

Q. Do you recall who made the decision within Schering to stop work on the Niacor-SR project?

A. No.

Q. Do you recall when that decision was made?

A. No.

Q. Prior to the end of March of 1998, did you tell anyone at Upsher-Smith that Schering was no longer pursuing Niacor-SR?

A. No.

Q. Do you know anybody at Schering who made that statement to Upsher-Smith prior to March of 1998?

A. Not that I'm aware of, no.

Q. Let's go back to the information you were given by Upsher-Smith before you did your commercial assessment of Niacor-SR between June 12th and June 17th. Let's turn to CX 1042.

Do you recall if there was any information in

this document about a cross-licensing agreement between Upsher-Smith and Kos?

A. No, I don't believe there was anything.

MR. EISENSTAT: At this time, Your Honor, I'm going to be working with an in camera document.

JUDGE CHAPPELL: Okay, at this time we are going to have to ask the public to leave the courtroom. We will be considering confidential information.

(The in camera testimony continued in Volume 18, Part 2, Pages 4306 through 4321, then resumed as follows.)

BY MR. EISENSTAT:

Q. While you were working on your commercial assessment of Niacor-SR from June 12th through June 17th, you never had any conversations with Ray Kapur, did you?

A. While I was doing my assessment?

Q. Between June 12th and June 17th, right.

A. That is correct.

Q. And before June 12th, you never had any conversations with Ray Kapur about Niacor-SR.

A. No.

Q. And while you were working on your commercial assessment of Niacor-SR from June 12th through June 17th, you never had any conversations with Mr.

Wasserstein, Jeffrey Wasserstein, did you?

A. That is correct.

Q. And before June 12th, you never had any conversations with Mr. Wasserstein about Niacor-SR.

A. That is correct.

Q. During the time you were working on your commercial assessment for Niacor-SR from June 12th to June 17th, 1997, you never had any conversations with anybody else at Schering besides Mr. Lauda about Niacor-SR. Is that correct?

A. That's correct.

Q. How long did you hold the position as I believe it's senior director of cardiovascular and CNS in global marketing?

A. From April of 1995 to September 2000.

Q. And I don't know if we ever said this on the record, so let me just ask it now just to make sure, the CNS and cardiovascular, the CNS, that stands for central nervous system?

A. That is correct.

MR. EISENSTAT: May I approach the witness, Your Honor?

JUDGE CHAPPELL: Yes, you may.

BY MR. EISENSTAT:

Q. Mr. Audibert, I'm going to hand you what's been

marked as CX 36, and this is sales information that I had gotten off of Schering's web site a few months ago, and it shows Schering-Plough Corporation Cardiovascular Product Sales (Dollars in Millions).

Have you ever seen data in this format for Schering?

A. I can't remember seeing it exactly in this format. I'm sure I've seen very similar information.

Q. Okay. This lists a number of products. The first product listed is called Imdur, I M D U R. Do you see that?

A. Yes.

Q. What is Imdur?

A. That is an extended release isosorbide mononitrate product used for the treatment of -- oral product used for the treatment of angina.

Q. And angina is what?

A. Angina is when patients experience chest pain through -- due to an insufficient amount of oxygen going to their heart muscle.

Q. Do you see the U.S. sales of Imdur in the year 2000?

A. 2000? Yes.

Q. About $117 million. Is that right?

A. For the year 2000, yes.

Q. And the international sales of Imdur in that same year were $3 million?

A. That's correct.

Q. Do you know why there was such a big difference between the international sales of Imdur and the U.S. sales of Imdur?

A. Yes, I believe we did not have international rights to that product. This was developed by another company.

Q. And so you only licensed the rights for that in the U.S.?

A. U.S. and I think Canada. That's what that $3 million may represent.

Q. Okay. And the next product on the list is Integrelin. Do you see that?

A. Yes.

Q. And Integrelin shows U.S. sales in the year 2000 of $159 million?

A. That's correct.

Q. And it shows international sales in that same year, 2000, of $13 million?

A. Yes.

Q. Do you know why there was such a big difference in the sales of Integrelin?

A. A number of different issues. One had to do

with the labeling we ended up getting from the FDA versus the labeling we got from international. There was a delay in the introduction of the product in Europe, and the price in Europe was much lower also, like half the price.

Q. The price in Europe was much lower than the price in the United States?

A. Half the price of the product that was priced in the U.S.

Q. What was the labeling issue?

A. The labeling issue was in the U.S., we had a broad indication for patients undergoing angioplasty as well as unstable angina, where in Europe at that time we just had a labeling for unstable angina, and the bulk of the business was on the angioplasty side.

Q. The next product listed is K-Dur. Do you see that?

A. Yes.

Q. And what's K-Dur?

A. That's an extended release nitroglycerin -- excuse me, extended release potassium chloride tablet.

Q. And that shows in the year 2000 sales of $287 million in the United States?

A. Yes.

Q. And $3 million internationally?

A. That's correct.

Q. Do you know why there was such a big difference there?

A. I don't think it was -- it was never marketed in Europe, primarily probably because we couldn't get the type of price in Europe that we could get in the U.S.

Q. And the next product is Nitro-Dur?

A. Yes.

Q. Is that the patch product you were talking about earlier?

A. That's correct.

Q. So, that's an extended release nitroglycerin patch that people wear?

A. I don't know if it's extended release, but it's a long-acting nitroglycerin patch, yes, that people wear.

Q. Okay. And sales of that in the year 2000 seem to be almost identical between the U.S. and the international. Is that right?

A. Yes.

Q. You testified earlier this morning that in November 1997, Kos' stock price fell. Do you remember that?

A. Yes.

Q. And you said that was correlated with analysts' reports of declines in estimates for Kos' sales of Niaspan. Is that right?

MR. NIELDS: Objection. I don't believe that's what he said.

MR. EISENSTAT: Well, let me avoid the objection.

BY MR. EISENSTAT:

Q. Why did Kos' stock price fall?

A. Well, as I mentioned, Kos at that point had announced their first quarter sales of Niaspan, which is the only product they were marketing, and their sales were very low, I mean below the expectation of everybody, and the reason I believe the stock price went down is all of a sudden the analysts started to wonder whether the sales potential of Niaspan would be what they originally thought the sales were going to be when they had the price much higher.

MR. EISENSTAT: One moment, Your Honor.

(Brief pause.)

MR. EISENSTAT: May I have just a moment, Your Honor?

JUDGE CHAPPELL: Yes, you may.

(Pause in the proceedings.)

(Commission Exhibit Number 1694 was marked for

identification.)

BY MR. EISENSTAT:

Q. Mr. Audibert, I'm going to hand you a document which I just have now marked as CX 1694, and this appears to be a report off the Dow Jones News Service. Do you see that?

A. Yes.

Q. And it talks about shares of Kos Pharmaceuticals plunging 46.5 percent?

A. Yes.

Q. And it gives an analyst's report on the lower sales. Is this the kind of report you were talking about?

A. I didn't have any particular report in my mind when I talked about the analysts, but in general, yes, it would be this type of thing.

Q. Do you see the line where they talk about, "Salomon Brothers' Uhl cited slower prescription volume for Niaspan because it has a staggered dispensing schedule. He also said Niaspan sales may be lagging because of the company's small in-house sales force of 109 people"?

Do you see that line?

A. Yes.

Q. And then under there he says, "He reduced his

sales expectations for Niaspan to $7 million in 1997 from $12 million and $46 million in 1998 from $92 million."

Do you see that?

A. Yes.

Q. Is that the kind of decline in the sales reporting you were talking about?

A. In general, yeah. I wasn't specifically thinking of this, but in general, yes.

Q. Now, not everybody at Schering-Plough had thought that the analysts' reports for Niaspan were what was going to happen, did they?

A. I don't know what everybody at Schering-Plough thought.

Q. Okay. The team that was working on the Niaspan product, they actually did sales forecasts, did they not?

A. I believe so.

Q. And did they do their own sales forecast or did they use what the analysts were predicting?

A. I'm not sure what they used to develop those sales forecasts.

Q. Let me have -- let me show you --

If I may approach the witness, Your Honor?

JUDGE CHAPPELL: Yes, you may.

BY MR. EISENSTAT:

Q. Let me show you what's been marked as CX 558. Have you ever seen this document before?

A. I don't have any specific recollection of seeing this.

Q. Do you know who Martin Driscoll, who this document is from, was?

A. Yes, he was the vice president in charge of Key Pharmaceuticals I believe at this particular time.

Q. Okay. Do you see -- do you see where he says in the first line of the third paragraph, "Although certain investment firms have publicly stated that 'Niaspan is a $250 million product', we don't necessarily share that view"?

A. Yes.

Q. And do you know what Kos' sales figures were in the beginning of -- or the end of 1997?

A. No, I don't remember what they were.

Q. Did you ever see Mr. Russo's estimates of what Kos' sales figures were going to be for Niaspan?

A. I don't know whether I ever saw them or not.

Q. Well, let me show you a demonstrative that was used by Mr. Nields in his opening, which shows April 1997 Niaspan Sales Projection, United States, Raymond Russo, Senior Director of Marketing - Cardiovascular.

Do you see that --

JUDGE CHAPPELL: I think you may want to zoom that in some.

MR. EISENSTAT: Excuse me, Your Honor?

JUDGE CHAPPELL: You are going to have to zoom in on that if you want him to look at that or if you want me to look at it, either way. Thank you.

BY MR. EISENSTAT:

Q. Do you see what his estimate for Niaspan sales were in 1997?

A. Yes.

Q. And what were they?

A. Assuming these are actual dollars, so $7,022,000.

Q. Okay. And that's approximately the same thing as the Dow Jones News Service report of -- where sales results were lowered to $7 million in 1997?

A. I'd have to go back and look.

MR. NIELDS: Are you asking him a question about -- I object that it's vague. It's unclear whether he's asking a question about this Dow Jones, that its sales were actually not $7 million or whether he's asking that's what the analysts had adjusted to their predictions to.

MR. EISENSTAT: Just that that's what the

analysts had adjusted their predictions to.

THE WITNESS: I'd have to go back and look.

BY MR. EISENSTAT:

Q. Do you have that Dow Jones report? Do you see the third paragraph up from the bottom where it says, "He reduced his sales expectations for Niaspan to $7 million in 1997"?

A. Yes, this one particular analyst, yes.

Q. And that's approximately the same number as Mr. Russo. Is that right?

A. Yes.

Q. And what's Mr. Russo's estimate for sales in 1998?

A. $48,247,000.

Q. And what was the analyst quoted in the Dow Jones News Service estimating for 1998?

A. He was -- in this document, it says that he's reducing his estimate from $92 million to $46 million.

Q. Okay.

One moment, Your Honor.

(Counsel conferring.)

MR. EISENSTAT: No more questions, Your Honor.

JUDGE CHAPPELL: Redirect?

MR. NIELDS: Yes, Your Honor.

JUDGE CHAPPELL: Mr. Eisenstat, you might want

to retrieve the in camera documents that are lying on the Bench, keep them secure. Thank you.

REDIRECT EXAMINATION

BY MR. NIELDS:

Q. Mr. Audibert, you were asked a few questions by Mr. Eisenstat on cross examination about Geltex and Cholestagel. Do you recall those questions?

A. Yes.

Q. Is Geltex a company?

A. Yes.

Q. Okay. So, when he was asking about Geltex, he was asking you about a company. Is that right?

A. Yes.

Q. And Cholestagel is a product that was in development at that company?

A. That's correct.

Q. And was Schering exploring the idea of actually buying the company?

A. That was one of the possibilities, yes.

Q. And Cholestagel, the product that Geltex had in development, that's a product for the treatment of cholesterol?

A. That's correct.

Q. And it's a bile acid sequestrant?

A. Yes.

Q. Is that sometimes referred to as a resin?

A. A resin, yes.

Q. Okay. And was there anything unusual about the gel -- about the Cholestagel resin?

A. Yes, my recollection of the Cholestagel product was Geltex had taken cholestyramine -- cholestyramine, as has been mentioned before, it's a resin, and it actually creates its pharmacological effect by literally binding with the bile acids in the gut, and by taking those acids out of the body, you reduce the amount of cholesterol that's available to produce.

The problem was, because of the way the drug works, there's several significant effects that take place. One, and the one that probably the most patients complain of, as one might imagine, when this substance physically binds the resins in the gut, it has to go somewhere, and these patients have very uncomfortable side effects. They have what they call steatorrhea, which is fat in the stools, and it's a very -- they have a lot of gassiness, bloating, diarrhea. It's very uncomfortable. So, that's one issue.

The other issue, and the reason, as I mentioned to Mr. Eisenstat regarding drug interactions, again, because of the way this drug works, it physically

adsorbs -- "ad" meaning it attaches -- adsorbs bile acid in the gut, it will also do this to drugs also. So, there are a number of drugs that patients commonly take, for example, Digitalis for their heart or leophylline (phonetic) for prevention of their -- to prevent clotting, these drugs have very narrow therapeutic indexes, and if you start now literally clamping onto those drugs in the gut, you will have less drug available to be effective in the patient.

So, knowing that, what Geltex had told us that they did at least, is they literally took the cholestyramine molecule and manipulated this molecule, as they described to us, they were hiding the binding sites of the molecule. So, basically cholestyramine is this molecule that works by binding with bile acids in the gut, and what they told us they were doing is by manipulating the molecule of cholestyramine, they left good binding sites open and they blocked the bad binding sites.

Now, this was their hypothesis to us. So, this was not a simple sustained release capsule. This was truly a manipulation of the molecule to allow some binding sites to exist, others to be blocked, and they were claiming by doing this, you would then get the beneficial effects of cholestyramine without the

negative effects associated with cholestyramine.

Q. But did this new formulation, twisting the molecule, did that create new issues that had to be explored?

A. Well, certainly the main one that had to be explored is was there -- did they validate their hypothesis? Was -- did, in fact, this drug have an impact on the absorption of drugs? Did it have a lower incidence of GI side effects? Did it have, as I said, the drug interactions?

And then the other issue that came up because of this and the reason I was asking for the tablet samples, that they -- based on some information we had been provided, the tablets were going to be quite large, again, because of the way they manipulated the tablets. Up to now, most of the cholestyramine had been administered to patients is in a gritty, sand-like substance that patients put into water and drink, and so it's not very desirable. So, they wanted to put it into a tablet form, which made a lot of sense, because patients would rather swallow a tablet then drink this gritty, sand-like substance.

The problem was the tablets they were manufacturing were quite large, and the fact that patients had to take four to six or four to eight, I

forget which number, tablets per day, the question is a patient is going to take four to six or four to eight of these large horse tablets on a daily basis, and these are issues one has to take into consideration as to whether the product will be acceptable in the marketplace.

Q. And did any of these issues apply to -- did any of these issues apply to Niacor-SR?

A. No.

Q. Now, Mr. Eisenstat asked you about a document that is -- has the exhibit number CX 1286, it's one of these documents about Cholestagel and Geltex, and if you look at --

Oh, Your Honor, I have just been advised, I think correctly, that this was an in camera document, so I guess I've got to go in camera in order to ask the witness about it.

JUDGE CHAPPELL: What about the last few answers? What about the last few answers about this product?

MR. NIELDS: Well, Your Honor, I think it -- that the horse has probably left the barn with regard to the oral. I believe what's actually been marked in camera is the document, and I think I best go in camera when we use the document.

JUDGE CHAPPELL: Okay. At this time I'll have to ask the public to leave the courtroom.

(The in camera testimony continued in Volume 18, Part 2, Pages 4322 through 4325, then resumed as follows.)

JUDGE CHAPPELL: Would someone notify the public, assuming anyone's out there? Thank you, ma'am.

BY MR. NIELDS:

Q. Do you have that in front of you?

A. SPX 2?

Q. Yes.

A. Yes.

Q. And is that your evaluation of Niacor-SR?

A. Yes.

Q. And is that what you did on June 17, 1997?

A. Well, the date -- I guess it's June 17th --

Q. I mean, you did it in June 1997.

A. Yes, yes.

Q. And again, referring to the sales projections that are at Table II at the back of that document, can you tell us what those sales projections for Niacor-SR represent, sir?

A. You mean what the sales numbers themselves represent? They represent my best judgment in terms of what I believe the sales of Niacor would be in those

territories for the years 1999 to 2008.

Q. And was that influenced by anything outside of your best business judgment about what those sales would be?

A. No.

MR. NIELDS: I have nothing further, Your Honor.

MR. CURRAN: Nothing for Upsher, Your Honor.

MR. EISENSTAT: I have just a couple of questions, Your Honor.

JUDGE CHAPPELL: Okay.

MR. EISENSTAT: First of all, if I may approach the witness and give him back -- it does deal with the in camera document, Your Honor.

JUDGE CHAPPELL: So, we are going back to in camera?

MR. EISENSTAT: Back in camera.

JUDGE CHAPPELL: I am going to have to ask the public to leave the courtroom once again, momentarily, I believe. Thank you.

(The in camera testimony continued in Volume 18, Part 2, Pages 4326 through 4330, then resumed as follows.)

JUDGE CHAPPELL: How long do you think your direct will be of the next witness?

MR. NIELDS: Your Honor, it will be a -- I think you've met her before, Ms. Diane Bieri, and she has informed me she expects it to be approximately 45 minutes.

JUDGE CHAPPELL: We are going to need an afternoon break. I'm just wondering if we should take it now since we have to cut off at 5:00 today.

MR. NIELDS: It might be worthwhile, because it is going to take us just a few minutes to set up I think with --

JUDGE CHAPPELL: Let's take a short break. We're in recess until 3:25.

(A brief recess was taken.)

JUDGE CHAPPELL: Schering, are you ready to call your next witness?

MR. NIELDS: Yes, Your Honor, we are going to call James Furniss, and as I think I mentioned to Your Honor this morning, he is a witness who will testify about pricing in overseas markets.

JUDGE CHAPPELL: Okay.

MR. NIELDS: And Diane Bieri will be posing him the questions.

JUDGE CHAPPELL: Let's proceed.

MR. NIELDS: Thank you.

MS. BIERI: Thank you, Your Honor.

JUDGE CHAPPELL: Please raise your right hand.

Whereupon--

S. JAMES FURNISS

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Thank you, have a seat, please.

State your full name for the record, please.

THE WITNESS: Stephen James Furniss.

JUDGE CHAPPELL: Thank you.

You may proceed.

MS. BIERI: Thank you. Good afternoon, Your Honor.

DIRECT EXAMINATION

BY MS. BIERI:

Q. Good afternoon, Mr. Furniss.

Mr. Furniss, can you tell us where you live?

A. I live in Kettering, Northhamptonshire in the United Kingdom.

Q. And what is your occupation?

A. I'm a consultant in the pharmaceutical industry.

Q. And where do you currently work?

A. My base is in Cambridge, England.

Q. And what company do you work for?

A. Cambridge Pharma Consultancy.

Q. What does Cambridge Pharma Consultancy do?

A. Cambridge Pharma Consultancy provides consultancy services to the pharmaceutical industry on a range of commercial issues.

Q. And are there any particular issues that you yourself specialize in there?

A. I specialize in pricing and reimbursement issues in European markets.

Q. And how long have you worked at Cambridge Pharma Consultancy?

A. Nearly five years.

Q. We are going to come back to your work at Cambridge Pharma Consultancy in a minute, but first I would like to ask you some questions about your other education and experience. Can you describe any college degrees that you hold?

A. I have a BA from Cambridge University.

Q. When did you receive that degree?

A. 1972.

Q. And following your graduation in 1972, where were you employed?

A. I was employed in the UK Department of Health and Social Services, now the Department of Health.

Q. Is it all right if we call it Department of

Health?

A. Yes.

Q. And how long did you work for the UK Department of Health?

A. For nearly 24 years.

Q. Did you hold any positions at the UK Department of Health relating to pharmaceutical products?

A. Yes.

Q. What was the first position that you held at the UK Department of Health relating to pharmaceutical products?

A. Head of the Pharmaceutical Services Branch.

Q. And what were your responsibilities -- I'm sorry, when did you hold the position of head of the Pharmaceutical Services Branch of the UK Department of Health?

A. From 199 -- 1988 to 1991.

Q. And what were your responsibilities as head of the Pharmaceutical Services Branch?

A. I was responsible for policy relating to the supply chain for pharmaceutical products, specifically the remuneration and reimbursement of community pharmacists and/or relationships with the wholesale elements. In addition, I was responsible for patient co-payments for pharmaceutical products.

Q. Did you have any responsibilities relating to the pricing of pharmaceutical products?

A. Yes.

Q. And what were those responsibilities?

A. I was responsible for the drug tariff, which is the monthly publication that sets the price for generic products in the UK market.

Q. Did you hold any other positions at the UK Department of Health after being head of the Pharmaceutical Services Branch relating to pharmaceutical products?

A. Yes.

Q. And what was your next position at the UK Department of Health relating to pharmaceutical products?

A. Head of the Pharmaceutical Industry Branch.

Q. And when did you hold the position as head of the Pharmaceutical Industry Branch?

A. 1991 to 1997.

Q. Can you just briefly describe for me your chief responsibilities as head of the Pharmaceutical Industry Branch?

A. Yes, I was responsible for the Government's relationship with the international pharmaceutical industry, specifically those companies operating in the

UK market. That included responsibility for the operation of the pharmaceutical price regulation scheme, which is the particular price control mechanism used in the UK. I also represented the UK Government on pharmaceutical issues with the European Commission in Brussels.

Q. Now, you mentioned that you were in charge -- that you were in charge of the Pharmaceutical Price Regulation Scheme. Is that correct?

A. Yes.

Q. And I think you described that as the system that controls the prices of pharmaceutical products in the UK?

A. Yes.

Q. Now, does that apply to branded pharmaceutical products?

A. Yes.

Q. And what did your responsibilities as the head of the Pharmaceutical Price Regulation Scheme involve?

A. I was responsible for the overall management of the scheme, and I participated in negotiations with the major pharmaceutical companies normally on an annual basis.

Q. Did the Pharmaceutical Price Regulation Scheme in the UK actually set the price of pharmaceuticals?

A. Not directly. The Pharmaceutical Price Regulation Scheme is primarily a profit control scheme rather than a price control scheme, so it controls the level of profits that companies may make from pharmaceutical products sold to the National Health Service in the UK.

Q. You also mentioned in your role as the head of the Pharmaceutical Industry Branch, excuse me, that you were representing the UK on a European committee. Is that correct?

A. That's correct.

Q. And in that work, did you have the opportunity to learn about pricing and reimbursement schemes in other countries outside of the UK, other European countries?

A. Yes, other members of the committee represented the other European member states. In most cases, they were people with responsibilities similar to myself, in other words, responsible for the price regulation schemes in those markets.

Q. Did you have other opportunities as head of the Pharmaceutical Industry Branch to become familiar with pricing and reimbursement schemes in other countries in Europe?

A. Yes, I spoke regularly about the UK system of

PPRS at international conferences. Typically at those conferences, there would be presentations from a number of countries describing the price reimbursement systems in both countries and issues with the operation of those systems.

Q. Now, did you hold any positions at the UK Department of Health after you were head of the Pharmaceutical Industry Branch?

A. No.

Q. And what did you do next?

A. I joined Cambridge Pharma Consultancy.

Q. What was the first position that you held at Cambridge Pharma Consultancy?

A. I was managing consultant charged with establishing a new practice area in European reimbursement.

Q. Can you just describe the role of the European reimbursement practice area at Cambridge Pharma Consultancy?

A. Yes, it's to advise pharmaceutical companies typically at the corporate level, so covering a number of European markets, on pricing and reimbursement issues relating to products, particularly new products, prior to entry into the market. The main responsibility is in developing strategies to achieve

commercially viable price levels and commercially viable reimbursement status for new products.

JUDGE CHAPPELL: Sir, you are going to need to speak up, please.

THE WITNESS: Okay.

BY MS. BIERI:

Q. Now, you said you began as a managing consultant at Cambridge Pharma Consultancy. Is that right?

A. That's correct.

Q. And when did you first join the company?

A. In 1997.

Q. And were you -- did you hold another position after you were managing consultant at Cambridge Pharma Consultancy?

A. Yes, my current position is senior vice president.

Q. And when were you promoted to senior vice president?

A. 1999.

Q. And have your responsibilities changed from the time you were managing consultant to your current position as senior vice president?

A. In terms of my specific practice area, no. In terms of my role in the overall management of the

company, yes.

Q. So, do you have an increased role in the overall management of the company now?

A. I do.

Q. Have you advised clients on pricing and reimbursement decisions in a particular geographic area throughout your work at Cambridge Pharma Consultancy?

A. Yes, I have, primarily in European markets, but occasionally in additional markets outside Europe. In particular, my practice area also covers Canada and Australia, because these are markets that operate in a way that is similar to European markets.

Q. How many projects would you say that you've worked on at Cambridge Pharma Consultancy that involve advising clients on pricing and reimbursement processes in Europe?

A. At least 60, probably more.

Q. Do you have any idea of how many such projects you work on per year?

A. Typically I would be working on 10 or 15 such projects in a year.

Q. And does your work typically focus on the pricing and reimbursement issues in a particular European country?

A. Usually it will be a number of markets, most

commonly what we refer to as the big five markets, that's France, Germany, Italy, Spain and the UK, but sometimes also covering additional markets. Occasionally I will do work in relation to one specific market.

Q. And since you've worked for Cambridge Pharma Consultancy, have you had opportunities to give any speeches or presentations on pharmaceutical pricing and reimbursement issues?

A. Yes, I still speak regularly at international conferences.

Q. And do you hold any honorary positions, sir?

A. I'm an honorary research associate at LSE Health, the London School of Economics.

MS. BIERI: Your Honor, at this time we offer Mr. Furniss as an expert on European pricing and the reimbursement procedures for pharmaceutical products.

JUDGE CHAPPELL: Any objection?

MR. SILBER: No objection, Your Honor.

MR. CURRAN: No objection.

JUDGE CHAPPELL: The motion is granted.

BY MS. BIERI:

Q. Mr. Furniss, were you retained to give an expert opinion in this case?

A. Yes.

Q. And on whose behalf were you retained?

A. I was retained on behalf of Schering-Plough.

Q. What is the subject on which you were asked to give your expert opinion in this matter?

A. I was asked to give an expert opinion on the assessment made as part of the commercial assessment for licensing of Niacor-SR on the aspects relating to the pricing and reimbursement assumptions for European markets.

Q. Briefly, sir, what is your understanding of the assumptions that Schering-Plough made when it was evaluating the licensing opportunity for Niacor-SR with respect to pricing and reimbursement in the European markets?

A. The basic assumption was that it would be possible to achieve a reimbursed status in European markets for Niacor-SR at a price of 50 percent of the price level of atorvastatin.

Q. And what is atorvastatin?

A. Atorvastatin is one of a class of products called the statins which are used for cholesterol management. It's the most widely used of that class. The brand name in the U.S. and some other markets is Lipitor. It has different brand names in some of the European markets.

Q. And did you reach an opinion as to whether these assumptions that Schering-Plough made regarding the reimbursement and pricing for Niacor-SR in Europe were reasonable?

A. Yes.

Q. And are you prepared to testify today about that opinion and your reasons for it?

A. Yes.

Q. We will just get into the details in a minute, but briefly, could you tell us what your opinion is as to Schering-Plough's pricing and reimbursement assumptions for Niacor-SR?

A. My assessment is that that pricing and reimbursement assumption was reasonable for some European markets, specifically UK and Germany, and it may be on the conservative side, in other words, it might have been reasonable to assume that a higher price was possible.

Q. And I'd like to go through the basis of your opinion and taking each of the major European markets one by one. Is that all right with you?

A. Yes.

Q. First of all, just to refresh us, what are the major European markets? What do you consider the major European markets?

A. France, Germany, Italy, Spain, UK.

Q. Okay, let's start with France. Have you prepared a chart to help us understand the basics of the system for pricing and reimbursement in France?

A. Yes.

Q. I'm showing you SPX 2243, and if you can look either in your book or on the screen, whichever's easier for you, is this the chart that you prepared to show us the basics of the system for pricing and reimbursement in France?

A. Yes.

Q. Does France automatically reimburse consumers for purchases of new pharmaceutical product as soon as the product is launched?

A. No.

Q. What would a company do if it were seeking reimbursement in France for a new pharmaceutical product?

A. The company will need to make a submission first to the Commission de Transparence, the Transparency Commission, and secondly to the committee, the pricing committee.

Q. Okay, let's take those one at a time. On your chart, you've mentioned the -- I'm not going to say the French -- the Transparency Commission is the English

pronunciation for that first committee, the CT, correct?

A. Yes.

Q. So, is it all right if we refer to it as the Transparency Commission?

A. Yes.

Q. Okay. And just so we're on the same page, did you prepare another chart for -- or key for some of the abbreviations that are listed on this first chart?

A. Yes.

Q. I'm showing you what has been marked as SPX 2244 now on your screen. Is that the key that you prepared that explains some of the abbreviations in the first chart?

A. Yes.

Q. Now, you mentioned the first step is -- in the process in France is that it would go to the Transparency Commission, the company would prepare a dossier, right?

A. Correct.

Q. And what would the Transparency Commission do with that dossier that the company prepared on a new product?

A. It would assess that dossier and reach an opinion. It may do that in dialect with the company,

but ultimately it will reach an opinion and will publish an assessment which will include two elements, the SMR, Service Medicale Rendu, which is an assessment of the seriousness of the disease area and the contribution that the product will make to the management of that disease, and the ASMR, the Amelioration du Service Medicale Rendu, which is a comparative assessment of the product in the context of other products available to treat the same condition.

Q. Now, you said that they may make this assessment in dialect with the company.

A. Yes.

Q. What did you mean by that?

A. The company will submit information. The company will propose what they believe is the appropriate level on the scales that the Transparency Commission uses in publishing its assessment. The Transparency Commission will appoint a person called the rapporteur, who will then engage in dialogue with the company, will seek additional information if they wanted it, will seek explanation, justification for some of the points that are raised in the dossier, if necessary, and will then make the assessment which is then ratified by the Commission as a whole.

Q. So, is it accurate to say that the assessment

made by the Transparency Committee is sometimes a matter of negotiation between the committee and the company?

A. Yes.

Q. Let's go back to the chart showing the general progress of this system. Does the Transparency Committee actually set the price regarding the new pharmaceutical product?

A. No.

Q. Who determines the price at which a new drug will be reimbursed in France?

A. The Comite Economique.

Q. And the English pronunciation of that is the Economic Committee?

A. Or sometimes called Pricing Committee, like terms.

Q. We will call it the Pricing Committee. What are the range of determinations that the Pricing Committee can make for the reimbursement of products in France?

A. Depending on the rating by the Commission de Transparence, which is one of the factors it takes into account, it can determine to reimburse the product at the standard level, to reimburse the product at a reduced level, or not to reimburse the product.

Q. What is the standard level of reimbursement?

A. The standard level of reimbursement in France is 65 percent reimbursement.

Q. And what factors will the Economic Committee or the Pricing Committee take into account to determine the level of reimbursement for the drug?

A. The critical factors are firstly the ratings that the drug has been given following the assessment by the Transparency Committee. Secondly, the likely impact that the drug will have within the market, in particular, whether it's likely to put pressure on the pharmaceutical budget, which is the Pricing Committee is responsible for. And thirdly, the price of other products in the market compared with the price sought by the company for this product.

Q. Now, can negotiations between the pharmaceutical company and the Pricing Committee affect the price that's assigned to the new drug?

A. Yes.

Q. And how could negotiations affect the pricing decision?

A. The price ultimately agreed is a result of negotiations between the Pricing Committee and the company. The company will submit its initial proposal. There will then be a period of dialogue. The company

will be asked to justify its proposal, and ultimately a conclusion will be reached through negotiation.

Q. Now, I think you've indicated on your chart here, which is SPX 2243, that the red highlighted path shows the path that Lipitor took through the reimbursement process, correct?

A. Correct.

Q. And again, Lipitor is the same thing as atorvastatin, right?

A. Correct.

Q. When did Lipitor become available in France?

A. It became available in France in 1998. That was later than other European markets, because there was a prolonged negotiation over price.

Q. And what does your chart indicate about the reimbursement level for Lipitor in France?

A. It received the standard level of reimbursement.

Q. Of 65 percent?

A. 65 percent reimbursement.

Q. And would you say that the 65 percent level is the level of which the majority of pharmaceutical products are reimbursed in France?

A. Yes, the vast majority are reimbursed at 65 percent.

Q. Now, your chart, SPX 2243, also indicates, and I'm looking at the bottom -- I guess the bottom right of the chart, it says, "Mutuelles will cover the difference between the reimbursed price and the full price."

A. Yes.

Q. What are mutuelles?

A. Mutuelles are organizations which provide complimentary health insurance which is adopted by some 80 percent of the French population, which will meet the difference between the amount that's reimbursed through the Government system and the full price of medicines.

Q. And did mutuelles cover the 35 percent of Lipitor not reimbursed by the Government?

A. Yes.

Q. Have you reached an opinion regarding whether Niacor-SR would have been reimbursed in France?

A. Yes.

Q. And what is that opinion?

A. My opinion is that it would have been reimbursed assuming a reasonable price level.

Q. And can you tell me at what percentage it would have been reimbursed, assuming a reasonable price level?

A. Yes, 65 percent.

Q. And why do you believe it would have been reimbursed at 65 percent?

A. Because all other products on the market for the management of high cholesterolemia are reimbursed at 65 percent. That's a clear indication that this is regarded as a serious disease area, and I would expect any other medicine treating that disease to be reimbursed at the same level.

Q. Would Niacor-SR have to offer greater clinical benefits than, for example, Lipitor, to be reimbursed in France?

A. No, unless they were seeking a price higher than that of the statins and Lipitor.

Q. And do you have an opinion as to whether Niacor-SR would have been reimbursed at a price of 50 percent of Lipitor's price in France?

A. My opinion is that that would have been an achievable price.

Q. And what's the basis for that opinion?

A. The basis for that opinion is that the expectation would be that Niacor-SR would have a similar level of clinical performance to the fibrates and would be used in the same sort of clinical way in treatment as the fibrates, and the fibrates are

reimbursed at that level, indeed in some cases a higher level than that.

Q. Have you prepared a chart that shows the prices of fibrates in France compared to the price equal to 50 percent of the price of Lipitor?

A. Yes.

Q. I'm showing you SPX 2241. Is this the chart that you prepared to compare the prices for all of the major European markets of fibrates and Lipitor?

A. Yes, yes.

Q. And those include France, correct?

A. Correct.

Q. And what does this chart show with respect to the prices for fibrates versus the prices equal to 50 percent of Lipitor in France?

A. It shows that in France, the price is slightly below 50 percent of the price of Lipitor for gemfibrozil and also for fenofibrate. Gemfibrozil is the most relevant one, because that's the most recently launched in the French market.

Q. So, is it your opinion then that Schering-Plough could have negotiated a price for Niacor-SR in France that's comparable to the price of gemfibrozil?

A. Yes.

Q. Okay, let's move on to pricing in Germany. Have you prepared a chart to illustrate pricing and reimbursement in Germany?

A. Yes.

Q. A small technical glitch, but I think we're back on track.

Is this chart, SPX 2245, the chart that you prepared for pricing and reimbursement in Germany?

A. Yes.

Q. Now, is reimbursement automatic at launch of the new pharmaceutical product in Germany?

A. Yes, it is.

Q. Are any pricing restrictions imposed on new pharmaceutical products when they're launched in Germany?

A. In general, no, and certainly for a patent protected product, no.

Q. And what about products that are not patent protected, are those products still reimbursed?

A. They are still reimbursed.

Q. And how does the reimbursement work for products that are not patent protected in Germany?

A. They may be included within the Reference Price System. Now, in the Reference Price System, a price is fixed for a group of medicines with identical or very

similar chemical structure and therapeutic effect, and a single price is agreed for reimbursement for any of the products within that grouping. If a product is priced at a higher level than that, then the patient is responsible for any excess payment above the agreed price.

Q. And how is the reference price determined?

A. There's a complex mathematical formula, but essentially it's a weighted average of the products included within that group.

Q. Is reimbursement ever refused for any products in Germany?

A. Products that are purely preventive in effect are not reimbursed within the German health care system, and occasionally other products will not be reimbursed following a specific decision.

Q. And in your opinion, would a sustained release niacin product with an indication for treatment of hypercholesterolemia be reimbursed in Germany?

A. Yes.

Q. Now, your chart, SPX 2245, shows the red highlighted path that Lipitor took through the German pricing system, correct?

A. Yes, that's correct.

Q. And was Lipitor subject to the Reference Price

System?

A. No.

Q. Have you reached an opinion regarding whether Niacor-SR would achieve reimbursement in Germany?

A. Yes, I have.

Q. And what is your opinion?

A. My opinion is that it would have been reimbursed in Germany.

Q. And do you have an opinion as to whether Niacor-SR would be reimbursed at a price equal to 50 percent of the price of Lipitor in Germany?

A. Pricing would be at the discretion of the company that launched the product in that market. There is no system of price control other than the reference pricing that I've just described. So, the proper question there really is whether it would achieve sales at the chosen price level rather than whether it would be reimbursed. It would be reimbursed.

Q. Would Niacor-SR have been subject to the Reference Price System in Germany in your opinion?

A. In my opinion, it would not for two reasons. The first is because I understand that there is patent protection associated with Niacor-SR in Europe, and secondly, products can only be included within the

Reference Price System if they can be grouped together. Niacor-SR does not have the same mode of action as other products used for the management of hypercholesterolemia, and I do not believe it would have been grouped with those products.

Q. And when you say it doesn't have the same mode of action, what do you mean?

A. I mean that it's -- it works by means of a different chemical pathway than other products.

Q. Is that related to its being a sustained release product?

A. No, that's primarily related to the nature of the molecule.

Q. Would fibrates ever be used as reference products in Germany for Niacor-SR?

A. For Niacor-SR, no, I don't believe they would.

Q. Okay, let's go back to SPX 2241. Does this chart show the prices for fibrates in Germany compared with the price for 50 percent of Lipitor?

A. Yes.

Q. And how do those prices compare?

A. The chart shows that both fenofibrate and gemfibrozil are priced at higher than 50 percent of the price of Lipitor in Germany.

Q. And does this support your opinion -- I'm

sorry, do you have an opinion that Schering-Plough could expect to market Niacor-SR at the price of 50 percent of Lipitor in Germany?

A. Yes, my opinion is they could expect to market successfully at least at that price, maybe somewhat higher.

Q. And is that opinion supported by this chart which shows the comparison with the fibrates?

A. Yes.

Q. Let's move on to Italy. Have you prepared a chart to illustrate pricing and reimbursement in Italy?

A. Yes.

Q. Let me show you what's been marked as SPX 2247, and is this the chart that you prepared for the pricing system in Italy?

A. It is.

Q. Is reimbursement in Italy for a new pharmaceutical product automatic on launch?

A. No.

Q. How does the company seek reimbursement in Italy?

A. Depending on the nature of the product, it will make a submission to CIPE Interministerial Pricing Committee or to CUF, the Commissione Unica Farmaco, or both.

Q. When would a company make a submission to CIPE?
A. Typically that's for generic products, that's for products which have been approved through the national procedure for the Italian market. All products that have been approved through European procedures will be submitted to CUF for decision.
Q. So, is it accurate to say that a submission for a new brand name product such as Niacor-SR would be made to CUF?
A. Correct.
Q. And what role does CUF serve?
A. It serves -- if you make the analogy with France, it serves the function of both the Transparency Commission and the Pricing Committee. In other words, it assesses the therapeutic benefit that the product offers and determines the price at which that product will be reimbursed.
Q. And are there different options for levels of reimbursement that the CUF could assign in Italy?
A. Yes.
Q. And what are those options?
A. There are essentially three classes -- or at the time when the assessment of Niacor-SR was being made, there were three classes, A, B and C. There is also a fourth class, H, which was hospital only, but if

we assume that that would not be appropriate for Niacor-SR, then there were three classes.

Class A is 100 percent reimbursement. Class B, which was subsequently abolished, was 50 percent reimbursement. And class C was nonreimbursed.

Q. And have you reached an opinion as to which class Niacor-SR would have fallen into?

A. Yes.

Q. And what is your opinion?

A. My opinion is that it would have been assigned to class A for reimbursement.

Q. And why do you believe that Niacor-SR would have been reimbursed at the full rate, class A?

A. Because all other products used for the management of hypercholesterolemia are within that class. Class C -- class B, which then existed, was primarily used for medicines for the management of mild or transient diseases, things like coughs and colds, stomach upsets, typically medicines that were also available over the counter.

Q. And as far as the pricing assumption, have you reached an opinion as to whether Niacor-SR was likely to be reimbursed at 50 percent of the price of Lipitor in Italy?

A. Yes, I have.

Q. And what's your opinion on that?

A. My opinion is that that's a reasonable assumption for the Italian market.

Q. And can you just tell us the basis for your opinion that it was likely that Niacor-SR would be reimbursed at the price equal to 50 percent of Lipitor in Italy?

A. Because other products for the management of hypercholesterolemia, specifically the fibrates, are reimbursed at about that price level.

Q. If we could go back to SPX 2241, returning to the chart that you prepared, does this chart illustrate the comparative prices of fibrates to 50 percent of Lipitor in Italy?

A. It does.

Q. And how do these prices compare?

A. Fenofibrate and bezafibrate are both priced below the price of 50 percent of Lipitor, but gemfibrozil is priced above the price of 50 percent of the price of Lipitor and is reimbursed in the Italian market.

Q. And I think you said earlier that gemfibrozil is one of the more recent products to be introduced, correct?

A. It is.

Q. Let's go to Spain now, and have you prepared a chart on pricing and reimbursement in Spain?

A. I have.

Q. Okay, let's go to SPX 2249. Is this the chart you prepared?

A. It is.

Q. Is reimbursement automatic at launch in Spain?

A. No.

Q. What does a company have to do to get reimbursement in Spain?

A. The company has to make a submission to the Ministry of Health and Consumer Affairs.

Q. And what does the Ministry of Health and Consumer Affairs do with the submission it receives from the company?

A. Assesses that submission. It will normally have one or two meetings with the company to discuss issues arising from that submission. It will then make a decision.

Q. And what is the range of reimbursement available in Spain?

A. There is a level of reimbursement for chronic diseases, for certain specified chronic diseases, at 90 percent. I do not believe that that would have been relevant to Niacor-SR. The standard level of

reimbursement in Spain is 60 percent, and then it's possible to determine not to reimburse the product or to restrict reimbursement to hospital if it's a product that is very expensive or requires a degree of specialist knowledge and use.

Q. What factors are taken into account in setting the price on a new pharmaceutical product in Spain?

A. There are a number of factors. Firstly, the therapeutic benefits that the new product offers. Secondly, the expected impact on the pharmaceutical budget. Third, the pricing of comparator products in the Spanish market. And fourthly, the price that that product has obtained in other European markets.

Q. Have you reached an opinion as to whether or not Niacor-SR would have achieved reimbursement in Spain?

A. Yes.

Q. And what is your opinion on that?

A. My opinion is that it would have achieved reimbursement in Spain. It's very unusual for products not to be reimbursed in Spain. The only issue is the price level, and there is sometimes quite strong negotiation on price.

Q. And have you also reached an opinion as to whether it would be reasonable that Niacor-SR could be

reimbursed at 50 percent of the price of Lipitor in Spain?

A. Yes.

Q. And what is your opinion on that?

A. My opinion is that that's a reasonable assumption.

Q. And what's the basis for your opinion that that's a reasonable assumption?

A. That's based on my understanding of the therapeutic benefits of the product. It's based on the price of comparator products, specifically fibrates, in the Spanish market. It's based on my assessment that Niacor-SR would be likely to achieve a similar price level in France and in Italy, which are the two comparator markets that carry the most weight in the Spanish assessment.

Q. Okay, let's go back to SPX 2241, if we could, and your now familiar chart. Mr. Furniss, does this chart show the prices comparing the fibrates and 50 percent of Lipitor in Spain?

A. Yes.

Q. And that comparison shows what?

A. It shows that while there's a range of prices, gemfibrozil is priced at somewhat above 50 percent of the price of Lipitor in Spain, and it is reimbursed in

that market.

Q. And finally, let's go briefly back to the United Kingdom. Have you prepared a chart to explain pricing and reimbursement in the UK?

A. Yes.

Q. I'm going to show you what's been marked as SPX 2251, and is this your chart for the UK?

A. Yes.

Q. Now, what happens with respect to reimbursement of a product in the UK when a new product is launched? Is it automatically reimbursed?

A. Yes, it's automatically reimbursed unless a specific decision is taken not to reimburse it.

Q. And when would a specific decision be taken not to reimburse a product in the UK?

A. Very rarely, but a product can be referred to the Advisory Committee on NHS Drugs, which is responsible for the Negative List, if it falls within one of the therapeutic categories covered by that committee. Those therapeutic categories are statutorily determined.

Q. Would -- in your opinion, would Niacor-SR be placed on the Negative List in the UK?

A. No, it is not within one of the therapeutic categories that are specified for the Advisory

Committee on NHS Drugs.

Q. Have you reached an opinion as to whether Niacor-SR's price could be set in the UK at 50 percent of the price of Lipitor?

A. Yes, on my understanding that it is a patent-protected molecule, I would expect that Niacor-SR would have freedom of pricing in the UK market. In other words, the company launching the product would be able to establish the price at whatever level they chose.

Q. And is that based -- would that be true even if it weren't patent protected in Europe?

A. No.

Q. If it were not patent protected in Europe, what would happen to -- would a price be set for Niacor-SR?

A. If there were no directly comparable product in the market, as there is not in the UK market, then the price would be a matter of negotiation with the Department of Health.

Q. And have you reached an opinion as to if Niacor-SR were not patent protected in the UK, whether they could negotiate a price equal to 50 percent of the price of Lipitor in the UK?

A. I would expect that to be achievable, yes.

Q. And what is the basis for your opinion there?

A. The basis for my opinion there is that there are a number of products for the treatment and management of hypercholesterolemia which are in the market at price levels higher than 50 percent of the price of Lipitor.

Q. Let's go back to SPX 2241 one more time, and does this chart illustrate your point comparing products, specifically the fibrates, with Niacor-SR in the UK?

A. Yes.

Q. And what does that comparison show?

A. It shows that bezafibrate is something below 50 percent of the price of Lipitor, that the other two fibrates, fenofibrate and gemfibrozil, are both priced substantially higher than 50 percent of the price of Lipitor. In fact, higher than the price of Lipitor.

Q. Now, this chart, SPX 2241, what time period do the prices on this chart reflect?

A. The prices on this chart reflect prices in the summer of 2001.

Q. And have you looked at any prices of fibrates in any European markets in 1997?

A. Yes, I've looked at the price of fibrates in the Spanish market in 1997.

Q. And could you just generally tell me what you

found when you compared the prices of the fibrates in Spain in 1997 compared to the 2001 prices?

A. The prices in Spain were somewhat higher in 1997 than they were in 2001 in both local currency and U.S. dollar terms.

Q. And have you compared prices for the Lipitor or atorvastatin in 1997 with prices in 2001?

A. Yes.

Q. And have you prepared a chart to illustrate the comparison between the 1997 prices of Lipitor and the 2001 prices?

A. I have.

Q. Okay, let's go to SPX 2242. Is this the chart that you've prepared?

A. It is.

Q. And what does this chart show about the price equal to 50 percent of Lipitor in '97 versus the price equal to 50 percent of Lipitor in 2001?

A. It shows that 50 percent of the price of Lipitor in 1997 was in every case higher when expressed in U.S. dollar terms than in 2001.

Q. And is this --

A. However, there are two elements in that comparison. One is local prices, and the other is the exchange rate, and clearly the exchange rates were

different in 1997 and 2001. That's -- for the commercial assessment that was undertaken in 1997 where the assessment was made in dollar terms, I believe that's an appropriate comparison.

Q. And is this consistent with what you would have expected in your experience with the prices of pharmaceutical products generally in these markets, this downward trend?

A. Yes. It's very unusual for pharmaceutical prices ever to increase in Europe, which means that in real terms, they get cheaper over time, because there is no allowance for inflation.

In addition, from time to time, governments will unilaterally reduce prices either for specific products, for example, in France, the price of Lipitor has been reduced in the autumn of 2001, or for products across the board, and that happened in Spain in 1998 and in 2000.

Q. And what does this downward trend in the price of Lipitor from 1997 to 2001 tell you about the original chart that you prepared using the 2001 prices?

A. It tells me that using 2001 prices, if anything, provides a stiffer test than using 1997 prices. In other words, it's a conservative approach.

Q. Now, in all of the five European markets that

you've discussed, you used fibrates as the most likely comparator products to Niacor-SR. Is that right?

A. That's correct.

Q. Why do you believe that fibrates are the most likely comparators?

A. Essentially there are three classes of therapy used for the management of hypercholesterolemia. There are the statins, such as Lipitor, there are the fibrates, and then there is cholestyramine. I used the fibrates as a comparator because it seems to me that they have a level of clinical performance which is most similar to that anticipated for Niacor-SR, because they are used in a similar way to Niacor-SR, and in particular, they might be expected to be used in some circumstances and in some patients in combination with statins.

Q. And is that true of Niacor-SR as well in your understanding?

A. That's true of Niacor-SR in my understanding.

Q. And why did you choose not to use statins as comparators?

A. Because statins offer a superior level of performance in terms of the extent of cholesterol lowering that they can provide, and I believe that made them an inappropriate comparator.

Q. And why did you not consider cholestyramine to be a comparator?

A. Because cholestyramine is less widely used in the management of high cholesterolemia. While it has that indication, it's not as widely used as the fibrates.

Q. Now, you mentioned -- I think I asked you this question with respect to France, but let me broaden it and ask it with respect to all the markets. Would Niacor-SR need to show clinical performance or therapeutic benefits greater than the statins to achieve reimbursement or pricing at 50 percent of the level of Lipitor?

A. No.

Q. Did you use any sustained release niacin or nicotinic acid products as comparators in your analysis?

A. No.

Q. Why not?

A. Because I was unable to identify any such products in European markets.

Q. So, you found no sustained release niacin products with a hypercholesterolemia indication on the market in any of these five major European markets, correct?

A. That's correct.

Q. And was that true as of 1997, to the best of your knowledge?

A. Yes.

Q. Were there any niacin products available over the counter in these major European markets in 1997?

A. Not as far as I could identify as a single product. There were multi-vitamin presentations which included niacin amongst other products, but I was unable to identify any product that contained niacin as the active ingredient.

Q. And would the pricing authorities in any of these big five European countries have looked at the price of over-the-counter multi-vitamin products as comparators for prescription sustained release Niacor-SR?

A. No. Those products are typically not reimbursed, and they would not be used as comparators.

Q. Now, if there were an immediate release niacin product on the market in the major European countries and it did not have a hypercholesterolemia indication, would the pricing authorities typically use that as a price comparator for Niacor-SR?

A. They may not use it as a price comparator, but that might be one of the factors they would want to

take into account in price negotiations. As a pragmatic, they would use whatever argument that is helpful to them.

Q. But it's possible that a company could negotiate a higher price for a sustained release niacin product, correct?

A. Correct.

Q. Have you been asked to -- in your work at Cambridge Pharma Consultancy, have you been asked to analyze the likely pricing and reimbursement in European markets before a company pursues a licensing opportunity?

A. Yes, on a number of occasions.

Q. And what type of analysis do you generally perform when you're projecting prices before a company chooses to in-license a product?

A. I would generally look at the indications and therapeutic characteristics actually anticipated of the licensing candidate. I would look at the markets those licensing candidates will be entering in terms of therapy and the products that are available within that market, how it compares with those products, and at the price levels that are prevalent in those markets.

Q. And if you had knowledge, general knowledge, of the therapeutic benefits of the product that were

issued and the prices for comparator products, you would know enough to come up with an estimate of the price at which a new product would -- could expect to be reimbursed for a company to pursue a licensing opportunity. Is that right?

A. That's correct.

MS. BIERI: I have no further questions.

JUDGE CHAPPELL: Does Upsher-Smith have any questions?

MR. CURRAN: No, Your Honor, thank you.

JUDGE CHAPPELL: Cross?

MR. SILBER: Yes, Your Honor.

Are you ready, Your Honor?

JUDGE CHAPPELL: Whenever you're ready. You may proceed.

CROSS EXAMINATION

BY MR. SILBER:

Q. Good afternoon, Mr. Furniss. My name is Seth Silber. I'm an attorney with the Federal Trade Commission.

You have done work for Schering prior to this litigation. Is that right?

A. Yes. Do you mind if I say Schering-Plough, because I've also done work for Schering, which is an entirely separate pharmaceutical company?

Q. That's fine.

And you've done work for Schering-Plough on a drug called Remicade. Is that right?

A. Right.

Q. And you have done work on a drug called PEG-Intron?

A. Correct.

Q. And you have done work on a drug called desloratadine?

A. Yes. Clarinex is the brand name.

Q. Okay, thank you.

Let's focus on desloratadine. In your work for Schering-Plough on that drug, you advised Schering about pricing and reimbursement for that drug in Europe?

A. That's correct.

Q. And in advising Schering on desloratadine, you looked at each member state that Schering was interested in individually.

A. That's correct.

Q. And you looked at each member state individually because each member state has a different pricing reimbursement system, correct?

A. That's one reason. That's not necessarily the only reason, that's correct.

Q. And the different systems is what you walked through in your presentation on your direct.

A. Yes.

Q. Okay. And you looked at each member state individually because some products that are widely prescribed in one member state might not be widely prescribed in another.

A. Exactly. The market may differ in addition to the pricing reimbursement systems differ, and there may be differences in the market itself.

Q. Okay. So, the market in different states may be different for a product.

A. Yes, although that varies by therapy area.

Q. Okay. In advising Schering on desloratadine, you looked at the prices of comparator products in each member state individually.

A. That's correct.

Q. And a company seeking reimbursement must negotiate a price separately with each member state.

A. That's correct.

Q. And that's part of the process you walked through in your direct.

A. Yes.

Q. In your work for Schering-Plough on desloratadine, you spent close to five months. Is that

right?

A. That's correct.

Q. And you spent those five months looking at issues on pricing and reimbursement for that drug for Schering-Plough.

A. Yes.

Q. And in addition to yourself, you had about five or six other employees spending at least part of their time looking at desloratadine?

A. Yes.

Q. And that was over the same five-month period?

A. That's correct.

Q. Are you familiar with a drug under development by Schering-Plough called ezetimibe?

A. I wouldn't say I'm familiar with it. I'm aware of it.

Q. Okay. You've heard of it?

A. I've heard of it, yes.

Q. And is it a cholesterol-lowering drug?

A. It is.

Q. Okay. And have you done any work for Schering-Plough concerning this drug?

A. No.

Q. If Schering-Plough was considering marketing this drug in Europe, would you expect them to do a

pricing analysis on a country-by-country basis?

A. I would.

Q. In the same way you did for Niacor-SR, correct?

A. Well, I would expect probably a more detailed analysis than that, depending on the stage at which the drug was in development and how much they were familiar with the indications and clinical attributes of the product.

Q. Okay. Well, the question I was really getting at was simpler, is just like for a drug like ezetimibe, you would expect them to do a country-by-country analysis.

A. Yes.

Q. And for --

A. I would advise them to do a country-by-country analysis. That may not be quite the same thing.

Q. Okay. And have you advised Schering, in fact, to do that when looking at pricing and reimbursement for any of the work you've done for them, to do a country-by-country analysis?

A. We did a country-by-country analysis for desloratadine, Clarinex, and although the context was rather different, we looked at Remicade on a country-by-country basis as well.

Q. Okay. Now, Schering-Plough didn't hire you to

look at Niacor-SR before they licensed the drug and paid $60 million for it, did they?

A. No.

Q. Now, if they had asked you to do work on this drug before they licensed the drug and paid $60 million for it, would you have advised them to look at it on a country-by-country basis?

A. That's difficult to answer, because it would depend on the circumstances. It would also depend on the time scale. On some occasions, when I've been asked by companies to evaluate a product as part of the input into a decision on licensing, that work's been done within a very constrained time frame, and it hasn't been possible to do a thorough country-by-country analysis.

Q. Have there been any circumstances where you have prepared a strategy for pricing and reimbursement that you have looked at the European Union as a whole without considering each member state separately?

A. Only when I've been dealing with a product at a very early stage in development.

Q. Do you recall --

A. Prior to phase III trials, for example.

Q. Okay. Do you recall your deposition testimony in this matter?

A. Yes.

Q. Let me show it to you.

Okay, the question at page 56, line 9 is:

"QUESTION: Have there been any circumstances where you have prepared a strategy for pricing and reimbursement that you have looked at the European Union as a whole without considering each member state separately?

"ANSWER: I can't think of an example where I've done that."

A. Right.

Q. Was that your testimony at your deposition?

A. That was.

Q. Did you ever correct that testimony?

A. No.

Q. And you were hired by Schering-Plough in this matter to assess whether pricing Niacor-SR at 50 percent of Lipitor was reasonable. That was your assignment.

A. Yes. Just a point of detail maybe, but --

Q. Certainly.

A. -- I wasn't hired by Schering-Plough. I was hired by Howrey on behalf of Schering-Plough.

Q. Okay, thank you for that clarification.

So, your assignment for the Howrey law firm was

to determine whether this one assumption in Mr. Audibert's commercial assessment was reasonable.

A. Correct.

Q. That's all you were doing. That's -- just looking at one assumption.

A. Yes.

MR. SILBER: Your Honor, may I approach?

JUDGE CHAPPELL: Yes, you may.

BY MR. SILBER:

Q. Mr. Furniss, I've handed you what's marked as CX 1044. Have you seen this document before?

A. I have.

Q. Is this the only document the Howrey law firm provided you from Schering's files?

A. From Schering's files, yes, I believe it was.

Q. Okay. What other documents did they provide you?

A. The other document they provided me was the expert testimony from Mr. Levy.

Q. Okay. Do you mean the expert report from Dr. Levy?

A. Yes.

Q. Okay. You received no other business documents from Schering's files?

A. Correct.

Q. You received no documents from Upsher's files?
A. Correct.
Q. You received no deposition testimony?
A. Only my own deposition testimony.
Q. Okay. You haven't seen the deposition testimony of any Schering witnesses?
A. Correct.
Q. You haven't seen the deposition testimony of any Upsher witnesses?
A. Correct.
Q. So, the only document you received in addition to Dr. Levy's report was this one document.
A. That's correct.
Q. Okay. And let's turn to the last page of this document, which is SP 1600047. Are you there?
A. Yep.
Q. Okay. And Paula, if you could just pull up all of the assumptions.
Now, the assumption you were asked to evaluate was simply the second to the last bullet point that says, "Product priced approximately 50% to atorvastatin," is that correct?
A. Yes.
Q. You weren't asked to evaluate any other of Mr. Audibert's assumptions?

A. I think implicit in that was reimbursed in most major markets as well.

Q. Okay. What about the first assumption, "Dossiers approved late 1998," were you asked to look at that assumption?

A. I was not.

Q. Would that be within your area of expertise?

A. If by "dossiers" you mean pricing reimbursement dossiers, yes. If you mean filing for regulatory approval for market access, market authorization, then while I have some expertise and experience in that area, that's not really my area of expertise.

Q. Okay, but if that concerned pricing reimbursement, that would be within your area of expertise?

A. Yes.

Q. So, you haven't determined whether that first assumption is reasonable, whether -- the dossiers approved in late '98, you haven't determined whether that's reasonable.

A. No.

Q. Do you know when Schering intended to file its dossiers in Europe?

A. No, I don't.

MS. BIERI: Your Honor, I'll just object that

that's vague. I'm not sure which dossiers counsel is referring to.

MR. SILBER: Your Honor, I'm just referring to the language in the document and asking him if he can testify to that assumption.

JUDGE CHAPPELL: Do you understand the question, sir?

THE WITNESS: I think I understand the question. I think the reference is to pricing reimbursement dossiers in those markets which require pricing and reimbursement dossiers.

JUDGE CHAPPELL: The objection is overruled.

Do you want her to read the question back?

MR. SILBER: If you could read the last question back.

JUDGE CHAPPELL: Yes.

(The record was read as follows:)

"QUESTION: Do you know when Schering intended to file its dossiers in Europe?

"ANSWER: No, I don't."

BY MR. SILBER:

Q. Just assume with me that Schering intended to file their dossiers at the very end of 1997, the very beginning of 1998, okay?

A. Okay.

Q. About how long does it take to get European approval for the drug itself, not pricing -- price, but just to get approval?

MS. BIERI: Your Honor, I'll just object that that's outside the scope of the witness' direct examination and also outside the scope of what the witness has been asked to testify about.

JUDGE CHAPPELL: I'll sustain that without some foundation.

MR. SILBER: Okay.

JUDGE CHAPPELL: I heard him talk a lot about approval but not about -- I heard him talk a lot about pricing but not about approval.

BY MR. SILBER:

Q. Okay. Do you have relevant knowledge about how long it takes to get a drug approved in Europe?

A. I can -- I have some relevant knowledge.

Q. Okay. Did you testify about that issue at your deposition?

A. Yes, I did.

Q. Okay.

A. I made it clear in doing so that this was not my specialist area of knowledge.

Q. Okay, but you are knowledgeable about these issues.

A. Yes.

Q. Okay. And approximately how long does it take to get approval for a drug in Europe?

MS. BIERI: Your Honor, I'll just renew my objection that this is beyond the scope of the witness' direct.

MR. SILBER: Your Honor, I'm trying to explore this to tie it in with how long it takes to get pricing reimbursement, so I'm trying to lay a foundation in order to get to that latter step of the timing of pricing reimbursement, which is clearly within his expertise.

MS. BIERI: Well, I think -- I'm sorry, Your Honor, but I think counsel could get there by simply asking about pricing reimbursement decisions and the timing of those decisions rather than asking the witness to give opinions based on regulatory approval.

JUDGE CHAPPELL: I'll overrule the objection to the extent he says he's going to connect it up.

MS. BIERI: Thank you, Your Honor.

BY MR. SILBER:

Q. Actually, maybe I can simplify this.

Assume with me that it takes about 12 to 15 months to get approval for a drug in Europe.

A. Yes.

Q. Okay? And does that sound like a reasonable assumption to you?

A. That sounds a reasonable assumption to me.

Q. Okay. So, if you file for approval right around let's just say the first of the year of 1998, you're going to be around the first of the year 1999 or three months into that year, according to my assumption, to get drug approval in Europe.

A. Yes.

Q. Okay. Now, that's not the end of the story in order to market the drug in certain of the countries in Europe. Is that correct?

A. That's correct.

Q. You need to get price reimbursement approval. Is that right?

A. You do in some markets.

Q. Okay, such as France, Italy and Spain, as you discussed in your direct.

A. Correct.

Q. And you talked about some specifics on price reimbursement. In France, you talked about the negotiations on Lipitor were prolonged. Is that right?

A. That's correct.

Q. And in Spain, you said there can be strong negotiation on price.

A. Yes.

Q. How long does that process take, to get price reimbursement approval in those three countries, in Spain, Italy and France?

A. It's very difficult to give a precise answer to that, and it certainly does depend to some extent on the level of price that you are trying to justify in the course of those negotiations. If the price is low enough, you'll get an answer very quickly. If you're going for a very high price, it can take a long time. I think typically in Italy and in Spain, one would expect the process to take between three and six months. In France, possibly somewhat longer.

Q. Okay.

A. But there's considerable variation around those figures.

Q. Okay. So, are we talking about a range of approximately three months to nine months, would that be fair?

A. Yes.

Q. Okay. So, my assumption that it takes 12 to 15 months just to get approval for the drug puts us at the beginning of '99 or the end of the first quarter of '99.

A. Yeah.

Q. And now we're adding one to three quarters to that.

A. For some markets.

Q. For France, Italy and Spain.

A. Not for UK or Germany, where you can launch immediately.

Q. Correct.

A. You have market authorization.

Q. And just to be clear, my questions are just about France, Italy and Spain.

A. Okay.

Q. Okay? So, we're talking about getting price reimbursement approval about halfway through '99 or at the end of '99 in France, Italy and Spain.

A. On the assumptions you've made, yes.

Q. Okay. Now, if you could look back in CX 1044 to SP 00045, and at the top under Sales Projections, and again, this is Mr. Audibert's analysis, it says, "As outlined in Table II, Niacor-SR is expected to be launched in early 1999 with 3rd-year sales of $114 million."

Do you see that?

A. Yes.

Q. And according to the discussion we just had, based on my assumption on how long it takes to get a

drug approved and the three to nine months you've indicated that may be appropriate to get price reimbursement in Spain, Italy and France, it's possible that Niacor-SR wouldn't be approved to be marketed after getting price reimbursement until the second half toward -- until towards the end of 1999.

A. In those markets, yes.

Q. Okay. And if that's true, then Mr. Audibert's assumption here is not correct.

A. Well, I'm not sure that that follows. I mean, I think there are two points there. Launched in early 1999, on the assumptions you've given, that would certainly be possible in UK and Germany, those are two large European markets.

Q. Just to be clear, my question is about France, Italy and Spain.

A. Okay, for France, Italy and Spain, on the assumptions you've given in terms of market authorization, then early 1999 would seem to be optimistic.

Q. Okay. And France, Italy and Spain are three of the big five, correct?

A. Correct.

Q. Now, in performing your analysis on Niacor-SR, you looked at comparators that the pricing

reimbursement authorities would likely use as part of a price determination.

A. Yes.

Q. And you looked at bezafibrate, fenofibrate and gemfibrozil.

A. Yes.

Q. And those are all fibrates.

A. Correct.

Q. And you also looked at the prices of the statin classes of drugs in trying to determine whether the statins were an appropriate comparator.

A. Yes.

Q. And you determined that the statins were not a good price comparator given that Niacor-SR did not have an LDL-lowering performance comparable to the statins.

A. That's correct.

Q. Now, in Mr. Audibert's analysis, what did he use as a comparator?

A. I don't recall what comparator he used apart from using 50 percent of the price of statins as one.

Q. So, the only possibility is a statin based on his document.

A. I can't -- I can't tell you what he had in mind in making his assessment.

Q. And you've never spoken to Mr. Audibert, have

you?

A. No.

Q. You never asked Schering's lawyers if you could talk to Mr. Audibert about his analysis?

A. No.

Q. So, you don't understand what Mr. Audibert did in reaching his 50 percent price assumption.

A. I understand only what's written here in this document.

Q. Okay. And the only drug he mentioned as a possible comparator is a statin, which you reject as a comparator.

A. I'm not sure that I've rejected it as a comparator. I've said in price terms that I don't believe it's feasible to expect Niacor-SR to achieve a price equivalent to the statins. What I have said in my testimony is that based on my assessment, I think a price of 50 percent of the statins is a reasonable assumption.

Q. But you didn't consider a statin to be a good comparator for Niacor-SR. Is that right?

A. That's correct.

Q. Let's take a look at one of your charts that you put together. This is the chart for France. Is that right?

A. That's correct.

Q. Which is SPX 2243. And at the top -- and you already discussed this with Ms. Bieri -- you talked about the CT, which is the Transparency Commission. Is that right?

A. That's correct.

Q. And the CT assesses the therapeutic value of the drug, right?

A. Yes.

Q. And then the CEPS sets the price.

A. Correct.

Q. And this flow chart shows that reimbursement is not automatic at launch.

A. Correct.

Q. And that's true for Italy and Spain also, is it not?

A. That's correct.

Q. How did Mr. Audibert evaluate how Schering was going to steer through this process for France, Italy and Spain where reimbursement is not automatic?

A. I can't answer that question.

Q. Why not?

A. I can't tell you what was in his mind. I can't tell you what prior experience or knowledge he had.

Q. And that's because you haven't spoken with him?

A. Correct.
Q. You haven't looked at his deposition testimony?
A. No.
Q. And you never asked to look at that information?
A. No.
Q. Do you know whether Mr. Audibert did a country-by-country analysis?
A. I don't know.
Q. Now, in your report, you critiqued Dr. Levy for not doing a country-by-country analysis, did you not?
A. Yes.
Q. And you don't know whether Mr. Audibert did a country-by-country analysis?
A. No, I don't know.
Q. So, you don't know whether he's subject to that same criticism?
A. No, I don't know.
Q. Okay, let me show you something from Mr. Audibert's deposition so that you can determine whether he is subject to that same criticism. Okay, this is from Mr. Audibert's deposition of October 24, 2001. This is page 151 at line 11:
"QUESTION: So, did you assume that your product would be reimbursed in Italy?

"ANSWER: I didn't do a specific, you know, country-by-country assessment, but most major markets, there's five -- you know, we use five major markets in Europe, the UK, France, Germany, Spain and Italy. I didn't go through country by country and make a, you know, sales assessment."

Do you see that?

A. Yes.

Q. So, it doesn't appear that Mr. Audibert did a country-by-country analysis?

A. Correct.

Q. So, he would be subject to the same criticism you had for Dr. Levy?

A. Yes.

MR. SILBER: That's all I have, Your Honor.

JUDGE CHAPPELL: Redirect?

MS. BIERI: No, Your Honor.

JUDGE CHAPPELL: Thank you, Mr. Furniss. You're excused.

THE WITNESS: Thank you.

MR. NIELDS: Your Honor, that's all we have for today. We appreciate Mr. Furniss getting out before the close of court.

JUDGE CHAPPELL: We're pretty much right on time, Mr. Nields, since we're leaving at 5:00. We will

adjourn until 9:30 tomorrow morning.

MR. NIELDS: Thank you, Your Honor.

(Whereupon, at 4:45 p.m., the hearing was adjourned.)

C E R T I F I C A T I O N O F R E P O R T E R

DOCKET/FILE NUMBER: 9297

CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

DATE: FEBRUARY 19, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: 2/20/02

SUSANNE BERGLING, RMR

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE